# DOCKET

# SUPREME COURT
OF THE UNITED STATES

No. 09-1273
Title: Astra USA, Inc., et al., Petitioners
v.
Santa Clara County, California
Docketed: April 21, 2010
Lower Ct: United States Court of Appeals for the Ninth Circuit
Case Nos.: (06-16471)
Decision Date: December 9, 2009
Rehearing Denied: February 11, 2010
**Questions Presented**

| ---Date--- | --------Proceedings and Orders---------- |
|---|---|
| Apr 21 2010 | Petition for a writ of certiorari filed. (Response due May 21, 2010) |
| May 3 2010 | Order extending time to file response to petition to and including June 21, 2010. |
| May 20 2010 | Brief amicus curiae of Chamber of Commerce of the United States filed. |
| May 21 2010 | Brief amicus curiae of Pharmaceutical Research and Manufacturers of America (PhRMA) filed. |
| Jun 21 2010 | Brief of respondent Santa Clara County, California in opposition filed. |
| Jul 6 2010 | Reply of petitioners Astra USA, Inc., et al. filed. |
| Jul 7 2010 | DISTRIBUTED for Conference of September 27, 2010. |
| Sep 28 2010 | Petition GRANTED. Justice Kagan took no part in the consideration or decision of this petition. |
| Oct 19 2010 | Consent to the filing of amicus briefs, in support of either party or of neither party, received from counsel for the petitioners. |
| Oct 20 2010 | Consent to the filing of amicus briefs, in support of either party or of neither party, received from counsel for the respondent. |
| Nov 8 2010 | SET FOR ARGUMENT ON Wednesday, January 19, 2011. |
| Nov 12 2010 | Brief of petitioners Astra USA, Inc., et al. filed. |
| Nov 12 2010 | Joint appendix filed. Statement of costs filed. |
| Nov 19 2010 | CIRCULATED. |
| Nov 19 2010 | Brief amicus curiae of the United States filed. (Distributed) |
| Nov 19 2010 | Brief amicus curiae of Chamber of Commerce of the United States of America filed. (Distributed) |
| Nov 19 2010 | Brief amicus curiae of APA Watch filed. (Distributed) |
| Nov 19 2010 | Brief amicus curiae of Pharmaceutical Research and Manufacturers of America (PhRMA) filed. (Distributed) |
| Nov 19 2010 | Brief amicus curiae of Washington Legal Foundation filed. (Distributed) |
| Dec 6 2010 | Record received from U.S.C.A. for 9th Circuit. (1 envelope) |
| Dec 6 2010 | Record for the U.S.D.C. for the Northern District of California is electronic. |
| Dec 13 2010 | Brief of respondent Santa Clara County, California filed. (Distributed) |
| Dec 17 2010 | Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed. |
| Dec 20 2010 | Brief amicus curiae of AARP, et al. filed. (Distributed) |
| Dec 20 2010 | Brief amici curiae of Contract Law Professors filed. (Distributed) |
| Dec 20 2010 | Brief amici curiae of Kansas, et al. filed. (Distributed) |
| Dec 20 2010 | Brief amicus curiae of Coalition of 340B Entity Groups filed. (Distributed) |
| Dec 20 2010 | Motion of Kansas, et al. for leave to participate in oral argument as amici curiae and for divided argument filed. |
| Dec 20 2010 | Brief amici curiae of Federal Courts Professors filed. (Distributed) |

| | |
|---|---|
| Jan 7 2011 | Motion of the Acting Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED. Justice Kagan took no part in the consideration or decision of this motion. |
| Jan 7 2011 | Motion of Kansas, et al. for leave to participate in oral argument as amici curiae and for divided argument DENIED. Justice Kagan took no part in the consideration or decision of this motion. |
| Jan 10 2011 | Reply of petitioners Astra USA, Inc., et al. filed. (Distributed) |
| Jan 19 2011 | Argued. For petitioners: Lisa S. Blatt, Washington, D. C., and Ginger D. Anders, Assistant to the Solicitor General, Department of Justice, Washington, D. C. (for United States, as amicus curiae.) For respondent: David C. Frederick, Washington, D. C. |

# PETITION FOR WRIT OF CERTIORARI

Supreme Court, U.S.
FILED
APR 21 2010
OFFICE OF THE CLERK

No. 09-

091273

IN THE

# Supreme Court of the United States

ASTRA USA, INC.; ASTRAZENECA PHARMACEUTICALS LP; AVENTIS PHARMACEUTICALS, INC.; BAYER CORP.; BRISTOL-MYERS SQUIBB CO.; PFIZER, INC.; SCHERING-PLOUGH CORP.; SMITHKLINE BEECHAM CORP.; TAP PHARMACEUTICAL PRODUCTS, INC.; WYETH, INC.; WYETH PHARMACEUTICALS, INC.; ZENECA INC.; and ZLB BEHRING LLC,

*Petitioners,*

*v.*

COUNTY OF SANTA CLARA,
ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

*Respondent.*

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, imposes a ceiling price that limits the prices that drug manufacturers may charge for drugs sold to specified health care facilities and entities, known as 340B entities. Section 340B requires the Secretary of Health and Human Services to enter into contracts setting forth the Act's pricing restrictions, and drug manufacturers are required to enter into those contracts as a condition of participation in Medicaid. 42 U.S.C. §§ 1396b(1)(10), 1396r-8(a)(1) & (b)(1)(A).

In the decision below, the Ninth Circuit held that the more than 2,700 covered 340B entities within the territory covered by the circuit have a private right of action under "federal common law" to enforce the Act's pricing requirements, even though the Act itself contains no express or implied private right of action. In direct conflict with the decisions of the Second, Sixth, and Tenth Circuits, the Ninth Circuit held that, notwithstanding the absence of a private right of action under the Act, a plaintiff may circumvent congressional intent under a federal common law claim that the plaintiff is a third-party beneficiary of a contract that embodies statutory requirements.

The question presented is whether, in the absence of a private right of action to enforce a statute, federal courts have the federal common law authority to confer a private right of action simply because the statutory requirement sought to be enforced is embodied in a contract.

## RULE 14.1 STATEMENT OF CORPORATE DISCLOSURES

**1) Astra USA, Inc., AstraZeneca Pharmaceuticals LP, and Zeneca Inc.**

Astra USA, Inc., AstraZeneca Pharmaceuticals LP, and Zeneca Inc. disclose that they are indirect, wholly owned subsidiaries of AstraZeneca PLC, a publicly held corporation.

**2) Aventis Pharmaceuticals Inc. and ZLB Behring LLC.**

Aventis Pharmaceuticals Inc. is an indirect subsidiary of sanofi-aventis, a French corporation that is publicly traded on the Paris and New York exchanges. No publicly held company owns more than 10% of the stock of Aventis Pharmaceuticals Inc.

ZLB Behring LLC is a wholly-owned subsidiary of ZLB Bioplasma HK Limited, a Hong Kong company. ZLB Behring LLC's ultimate parent is CSL Limited, a publicly held Australian company with shares issued on the Australian Stock Exchange.

**3) Bayer Corporation.**

Bayer AG, a publicly held corporation headquartered in Leverkusen, Germany, is the parent corporation of Bayer Corporation, one of the appellees in this action. There is no publicly held corporation that owns 10% or more of Bayer AG's stock.

4) Bristol-Myers Squibb Company.

Bristol-Myers Squibb Company makes the following Corporate Disclosure Statement:

i) Bristol-Myers Squibb Company has no parent corporation.

ii) No publicly held company owns 10% or more of the stock of Bristol-Myers Squibb Company.

5) Merck & Co., Inc.

On November 3, 2009, "Schering-Plough Corporation" changed its name to Merck & Co., Inc. Merck & Co., Inc. states that (i) it has no parent company and (ii) there is no publicly held corporation owning 10% or more of its stock.

6) Pfizer Inc.

Pfizer Inc. makes the following Corporate Disclosure Statement:

i) Pfizer Inc. has no parent corporation.

ii) No publicly held company owns 10% or more of the stock of Pfizer Inc.

7) SmithKline Beecham Corp.

SmithKline Beecham Corp., now known as GlaxoSmithKline LLC, and which does business under the name GlaxoSmithKline, discloses that it is owned, through several levels of wholly owned subsidiaries, by GlaxoSmithKline plc, a publicly held English limited company. To the knowledge of GlaxoSmithKline LLC, none of the shareholders of

GlaxoSmithKline plc owns beneficially 10% or more of its outstanding shares.

**8) TAP Pharmaceutical Products Inc.**

TAP Pharmaceutical Products Inc. hereby discloses that on May 1, 2008 TAP Pharmaceutical Products Inc. became a wholly-owned subsidiary of Takeda America Holdings, Inc. On July 1, 2008, TAP Pharmaceutical Products Inc. merged into Takeda Pharmaceuticals North America, Inc., which is a wholly-owned subsidiary of Takeda America Holdings, Inc.

**9) Wyeth, Inc. and Wyeth Pharmaceuticals Inc.**

Wyeth and Wyeth Pharmaceuticals Inc. provide the following corporate disclosure:

i) Pfizer Inc. is the ultimate parent corporation of Wyeth LLC (sometimes identified as Wyeth Inc.). Wyeth Pharmaceuticals Inc. is a wholly owned subsidiary of Wyeth LLC.

ii) Pfizer Inc. owns ten percent (10%) or more of Wyeth LLC's stock.

iii) Wyeth LLC is not a party to any merger agreements with publicly held corporations at this time.

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Centers for Medicare and Medicaid Services, Medicaid Drug Rebate Program Overview, http://www.cms.gov/MedicaidDrugRebateProgram/ ..... 5

UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, MEDICAID DRUG REBATE PROGRAM, INADEQUATE OVERSIGHT RAISES CONCERNS ABOUT REBATES PAID TO STATES 1 (Feb. 2005), *available at* http://www.gao.gov/new.items/d05102.pdf ..... 5

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## OPINIONS BELOW

The decision of the court of appeals is reported at 588 F.3d 1237. App., *infra*, 1a-29a. The previous opinion of the court of appeals is reported at 540 F.3d 1094. App., *infra*, 30a-58a. The unreported district court decisions reviewed by the court of appeals are set forth at App., *infra*, 79a-96a and 97a-124a.

## JURISDICTION

The court of appeals' decision was entered on December 9, 2009. App., *infra*, 1a. A petition for rehearing was denied on February 11, 2010. App., *infra*, 125a. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

## STATUTORY PROVISIONS INVOLVED

The relevant provisions of Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, and Section 1927 of Title XIX of the Social Security Act, 42 U.S.C. § 1396r-8, are set forth at App., *infra*, 127a-164a.

## INTRODUCTION AND SUMMARY

The Medicaid Act requires all drug manufacturers whose outpatient drugs are covered by Medicaid to enter into contracts with the Secretary of Health and Human Services (HHS). Those agreements are known as Medicaid Rebate Agreements, and under them the manufacturers agree to provide drug rebates to States. Section 340B of the Public Health Service Act requires the same drug manufacturers to enter into a separate contract with the Secretary, known as the Pharmaceutical Pricing Agreement ("PPA"), under which the manufacturers agree to provide deeply discounted prices to certain health care providers and entities referred to as "340B entities." The Medicaid Act specifies the amount of rebates owed to States under the Medicaid program,

and the 340B Act specifies the formula for the ceiling prices that apply to purchases by 340B entities. Both the Medicaid rebate amounts and the Section 340B ceiling prices are based on the drug manufacturers' Average Manufacturer Price ("AMP") and Best Price as prescribed by the Medicaid Act. 42 U.S.C. §§ 256b, 1396r-8. Those statutory requirements can be enforced by the Secretary, but there is no provision—express or implied—for enforcement by any private parties.

The Ninth Circuit, in the decision below, held that federal common law confers on 340B entities the right to sue to enforce the statutory requirement that drug manufacturers accurately report AMP and Best Price for all Medicaid covered drugs and ceiling prices for all Section 340B drugs, *even though the 340B Act itself concededly confers no private right of action to sue.* The court of appeals reasoned that although there is no implied right of action to enforce the statutory requirement, 340B entities have a federal common law claim for breach of contract as third-party beneficiaries under the agreements between manufacturers and the Secretary under the 340B Act. The court of appeals thereby created under the federal common law the right to enforce the 340B Act's drug pricing provisions where the statute itself confers no such right. App., *infra*, 3a, 8a, 29a.

The Ninth Circuit's decision deepens an existing 5-3 circuit conflict on whether the absence of an implied right of action precludes reliance on a common law breach of contract claim to enforce the requirements of the statute. The Ninth Circuit's recognition of a common law claim directly conflicts with the decisions the Second, Sixth, and Tenth Circuits, which have squarely held that the absence of an implied private right of action under a statute forecloses common law third-party beneficiary

claims. *Grochowski v. Phoenix Constr.*, 318 F.3d 80 (2d Cir. 2003); *Hodges v. The Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414 (10th Cir. 1984); *Hoopes v. Equifax, Inc.*, 611 F.2d 134 (6th Cir. 1979). By contrast, five other circuits, including the Ninth Circuit, have held that common law third-party-beneficiary principles may provide a private right to enforce a statutory requirement even in the absence of an implied right under the statute. *Dewakuku v. Martinez*, 271 F.3d 1031 (Fed. Cir. 2001); *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir. 1985); *Nguyen v. The U.S. Catholic Conf.*, 719 F.2d 52 (3d Cir. 1983); *Perry v. Housing Auth. of Charleston*, 664 F.2d 1210 (4th Cir. 1981); *Falzarano v. United States*, 607 F.2d 506 (1st Cir. 1979). The question presented is of paramount importance and recurs frequently under a number of federal statutes, including the Medicaid Act and 340B Act, that implement congressional mandates through contracts between the United States and private parties.

The court of appeals' recognition of a private right of action to enforce the 340B Act's drug pricing provisions has immediate and profoundly adverse consequences on the administration of both the drug rebate program under the Medicaid Act and the drug ceiling price program under the 340B Act. Both programs use the same drug pricing components and employ contracts to implement the statute. A private right of action under the Section 340B program would permit potentially 14,500 entities nationwide (of which approximately 2,700 reside in states within the Ninth Circuit), that spend $4 billion annually on outpatient drugs, to sue hundreds of drug manufacturers based on the manufacturers' pricing and sales data for more than 35,000 pharmaceutical products sold pursuant to those federal programs. *See infra*, pp. 5-7, 22.

The Ninth Circuit's decision ignores Congress's considered judgment that a private right of action would directly interfere with the government's ability to administer both the Medicaid Drug Rebate and Section 340B ceiling price programs. The Executive Branch also advised the Ninth Circuit that a private suit would disrupt its administration of *both* programs and risk the imposition of inconsistent obligations on the manufacturers whose sales HHS is charged with regulating. The court's ruling also inflicts immediate, enormous, and costly burdens on drug manufacturers that are now exposed to suits that neither they nor the government imagined. This Court's intervention is warranted to prevent the court of appeals' decision from wreaking havoc on these two critical federal health care programs.

The Ninth Circuit's holding also is patently wrong. "There is no general federal common law." *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). Only Congress has the authority to create a private right of action to enforce a statutory obligation, and the incorporation of that obligation into a contract does not create a right of action to enforce the underlying statute. Under no circumstances can federal common law create a private right to enforce a statute that does not itself supply that right either expressly or impliedly. *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001); *Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1102 (1991); *Wheeldin v. Wheeler*, 373 U.S. 647, 651 (1963). The Ninth Circuit's disregard of those settled principles calls out for this Court's correction.

## STATEMENT

### A. STATUTORY FRAMEWORK

This case arises under two interrelated federal programs for outpatient drugs—the Medicaid Drug

Rebate Program and the Section 340B Drug Ceiling Price Program. The Medicaid Act requires drug manufacturers to calculate and report the AMP and Best Price for Medicaid covered drugs, which in turn are used to calculate the ceiling price for Section 340B drugs. Neither program provides a private right of action to enforce the statutory drug pricing requirements.

### 1. The Medicaid Drug Rebate Program

The Medicaid Act prohibits federal financial participation under Medicaid "with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8" under which manufacturers pay rebates to States. 42 U.S.C. § 1396b(i)(10); *id.* § 1396r-8(a)(1), (b)(1)(A). Approximately 550 manufacturers have entered into rebate agreements with the Secretary covering more than 35,000 drugs, and manufacturers in 2002 paid approximately $5.6 billion in rebates to States.[1]

The Medicaid Act sets forth a drug pricing formula that determines the amount of rebates manufacturers owe to States for covered outpatient drugs. The Act's drug pricing provisions provided, for the time period relevant to this case, that if the drug is either a "single source drug" or an "innovator multiple source drug," the rebate due on each unit paid under a state plan is typically either (a) the

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[1] Centers for Medicare and Medicaid Services, Medicaid Drug Rebate Program Overview, http://www.cms.gov/MedicaidDrugRebateProgram/; UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE, MEDICAID DRUG REBATE PROGRAM, INADEQUATE OVERSIGHT RAISES CONCERNS ABOUT REBATES PAID TO STATES 1 Feb. 2005), *available at* http://www.gao.gov/new.items/d05102.pdf.

difference between the AMP and the manufacturer's Best Price, defined as the lowest price available (with some exceptions) from the manufacturer to any private purchaser or governmental entity within the United States, or (b) 15.1% of the AMP, whichever is greater. *Id.* § 1396r-8(c)(1)(A), (B) & (C) & (c)(2). For other drugs, the rebate is 11% of the AMP. *Id.* § 1396r-8(c)(3).

The Act requires manufacturers to report quarterly to the Secretary the AMP and Best Price for each of its "covered outpatient drugs." *Id.* § 1396r-8(b)(3)(A). The Act permits the Secretary to "survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices reported." *Id.* § 1396r-8(b)(3)(B). For the relevant period in this case, the Act also provided that "[n]otwithstanding any other provision of law, information disclosed by manufacturers * * * is confidential and shall not be disclosed by the Secretary * * * in a form which discloses the identity of a specific manufacturer * * * [or] prices charged for drugs by such manufacturer." *Id.* § 1396r-8(b)(3)(D).

### 2. The Section 340B Drug Ceiling Price Program

Section 340B of the Public Health Service Act of 1992, 42 U.S.C. § 256b, requires drug manufacturers to offer discounted drug prices to certain hospitals and clinics, so-called "safety net providers," that receive federal funds ("340B entities"). In 2005 alone, 340B entities spent $4 billion for drugs covered by the Section 340B program.[2] Over 800

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[2] Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency, Hearing Before the H. Comm. on Energy and Commerce Subcomm. on

drug manufacturers participate in the Section 340B program.[3]

In order for outpatient prescription drugs to be covered by Medicaid, drug manufacturers must sign an agreement consenting to the ceiling price set by the 340B Act. 42 U.S.C. § 1396r-8(a)(1), (5). Incorporating the same AMP and Best Price pricing methodology of the Medicaid Rebate Program, the 340B Act provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which" the manufacturer may not charge to any 340B entity an amount that exceeds "the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. § 1396 *et seq.*] in the preceding calendar quarter, reduced by [a] rebate percentage." *Id.* § 256b(a)(1). The "rebate percentage" is defined as the "average total rebate required under" the Medicaid Rebate Program "with respect to the drug * * * during the preceding calendar quarter; divided by * * * the average manufacturer price for such a unit of the drug during such quarter." *Id.* § 256b(a)(2)(A)(ii). Because of this ceiling price, 340B entities receive significant discounts.

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Oversight and Investigations 1 (Dec. 15, 2005) (testimony of Stuart Wright, Deputy Inspector General for Evaluation and Inspections Office of Inspector General, U.S. Department of Health and Human Services), *available at* http://archives.energycommerce.house.gov/reparchives/108/Hearings/12152005hearing1739/Wright.pdf.

[3] 2010 Quarter 2 Statistics for 340B Covered Entities (Apr. 1, 2010), *available at* ftp://ftp.hrsa.gov/bphc/pdf/opa/stats_2010_QTR_2.pdf.

As instructed by the Act, Section 340B's ceiling price requirements are set forth in a Pharmaceutical Pricing Agreement, which is a form contract prepared by HHS's Health Resources and Services Administration (HRSA). App., *infra*, 165a-181a. The PPA expressly incorporates by reference the manufacturer's statutory drug pricing obligations to report AMP and Best Price in accordance with the Medicaid Act's drug rebate provisions. *Id.* at 170a-71a (PPA ¶¶ II(a)-(d)). The PPA also provides that the Secretary is entitled to "reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the agreement." *Id.* at 171a (¶ II(e)).

If the Secretary believes that a manufacturer "has not complied" with Section 340B's requirements, "or has refused to submit reports, or has submitted false information," the Secretary "may initiate [an] informal dispute resolution process." *Id.* at 174a (¶ IV(c)). If the Secretary's allegation proves well founded, "the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate" the PPA. *Id.* The PPA provides that the agreement "shall be construed in accordance with Federal common law." *Id.* at 180a (¶ VII(g)).

## B. PROCEEDINGS BELOW

1. Petitioners are nine of the largest pharmaceutical manufacturers in the world. They were sued in this putative class action by the County of Santa Clara, California, on behalf of itself and other California counties that have responsibility for funding public hospitals, affiliated pharmacies, community health centers, and other public healthcare providers that fund the costs for prescription drugs through the Section 340B program. The County initially filed suit in state court, alleging that petitioners violated the ceiling

prices set forth in Section 340B. Petitioners removed the suit to the U.S. District Court for the Northern District of California, which dismissed the state-law claims. The County amended the complaint to add a breach of contract claim alleging that "[a]s the intended beneficiaries of the PPA," the class members were "entitled to damages they sustained as a result of [the petitioners'] breach of contract." Second Am. Compl. ¶ 104.

After again dismissing the state law claims, the district court dismissed the breach of contract claim under the PPAs, holding that neither the statute nor the PPA reflects an intent to bestow on private parties the right to sue to enforce the Act's pricing requirements. App., *infra*, 119a. With respect to the plaintiff's argument that class members are intended beneficiaries of the PPA, the court observed that it "strains credulity" to suggest that petitioners would have agreed to face the threat of "a crushing number of lawsuits" from "more than 12,000 covered entities."[4] *Id.* at 116a. The County appealed the dismissal of the breach of contract claim under the PPA.

2. The Ninth Circuit reversed and held that "federal common law" provides a breach of contract action for 340B entities to enforce the Act's drug pricing provisions as incorporated into the PPA. App., *infra*, 38a, 50a, 54a, 55a. In so holding, the court of appeals held that 340B entities "are intended

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[4] Since the district court's decision, the number of 340B entities has increased significantly to more than 14,500 nationwide. Additionally, the recently enacted Patient Protection and Affordable Care Act further increases the number of eligible 340B entities. *See infra*, pp. 22-23.

direct beneficiaries of the PPA and have the right as third parties to bring claims for breach of that contract." *Id.* at 36a. The court further held "that allowing such suits under the PPA is consistent with Congress' intent in enacting the Section 340B program, *even though the statute itself does not create a federal private cause of action.*" *Id.* (emphasis added). The court of appeals reasoned that "the right to sue inheres in one's status as an intended beneficiary." *Id.* at 39a. The Ninth Circuit also observed that the claim "presents no far-reaching question that requires expertise or uniformity in administration" of the drug ceiling price program because 340B entities could challenge ceiling prices based only on "the average manufacturer price *reported* to the Secretary" and could not "claim that the reported figure itself was somehow erroneous." *Id.* at 57a.

On remand, the district court interpreted the court of appeals' statement that the suit involved only the prices "reported to the Secretary" to bar disclosure of the drug manufacturers' underlying pricing data and the methods by which petitioners derived the AMP and Best Price figures reported to the Secretary. App., *infra*, 80a-81a. On interlocutory appeal, the Ninth Circuit invited the views of the Secretary of HHS concerning whether the case should be stayed and referred to the Secretary under the doctrine of primary jurisdiction. *See* Brief of the United States of America as Amicus Curiae in Support of the Judgment Below, *County of Santa Clara v. AstraZeneca Pharm. LP*, No. 09-15216, 2009 WL 4089524 (9th Cir. Oct. 27, 2009) ("Gov't Br.").

3. In response to the court of appeals' invitation, the United States, setting forth the considered judgment of the Secretary of HHS, expressed the view that it "never imagined that a 340B entity could bring a third-party beneficiary lawsuit" and that

such a suit would confer "rights never intended by the PPA signatories." *Id* at *9, *12. The agency also concluded that discovery in the suit was barred by the Medicaid Act's requirement that the Secretary ensure the confidentiality of drug manufacturers' pricing and drug sales information underlying the calculation of AMP and Best Prices. *Id.* at *12; *see* 42 U.S.C. 1396r-8(b)(3)(D).

The government also explained that the Medicaid Drug Rebate program has conferred considerable discretion on drug manufacturers to make reasonable estimates in calculating the AMPs and Best Prices under the Medicaid Act, which are in turn used to calculate ceiling prices under the 340B Act. Gov't Br., 2009 WL 4089524, at *6. As a result, the government explained that the recognition of a private right of action to enforce the Acts' pricing requirements would interfere with the agency's exclusive responsibility to administer both programs on a nationwide, uniform basis. *Id.* at *11 ("allowing suits like this would threaten the orderly operation of *both* programs" (emphasis in original)).

The government further explained that the programs create conflicting incentives for beneficiaries under the respective programs. The government thus observed that while relatively high AMPs generally increase the price that manufacturers may charge 340B entities (to the *detriment* of those 340B entities), high AMPs also increase the manufacturers' much larger rebate obligations to the States (which *benefits* the Medicaid program). *Id.* at *15. Those conflicting incentives, the government observed, highlight the need to leave the administration and enforcement of the 340B Act and Medicaid Act where Congress placed it, *i.e.*, with the Secretary of HHS, who has the expertise to resolve complex issues of pricing

methodology and difficult issues of statutory interpretation under both programs. *Id.*

4. The Ninth Circuit issued a superseding decision that reissued the panel's earlier decision but struck the language that had suggested the suit was limited to only the drug pricing information reported to the government. App., *infra*, 1a-29a. Although the court of appeals had invited the agency's participation, the superseding decision neither discussed nor deferred to the agency's express objection to the Ninth Circuit's recognition of a common law right of action under the 340B Act.

## REASONS FOR GRANTING THE PETITION

In a decision with dramatic and sweeping consequences, the Ninth Circuit has held that federal common law creates out of whole cloth a private right of action for several thousand public and private health care facilities and providers to sue drug manufacturers whose outpatient drugs are covered by Medicaid. This Court should review and reverse the Ninth Circuit's decision for three reasons.

First, the court of appeals' holding squarely conflicts with the decisions of other courts of appeals. The Ninth Circuit premised its creation of a cause of action to enforce a statute that does not itself confer one on the common law principle that "intended beneficiaries" of a statutory contract may sue to enforce the statutory requirements embodied in the contract. While other circuits have endorsed that approach, the Second, Sixth, and Tenth Circuits in sharp contrast have held that such a suit is an impermissible end-run around the absence of an implied private right of action under the statute and therefore have rejected the very approach embraced by the Ninth Circuit in this case.

Second, the court of appeals' creation of a private right of action for 340B entities to enforce the drug pricing provisions of *both* the 340B Act and the Medicaid Act has vast implications and risks disrupting the approximately $30 billion Medicaid program for outpatient prescription drugs. The statutes contain no private right of action; instead, they confer on the Secretary considerable discretion to apply agency expertise and administer a complex statutory framework. A private right of action subverts congressional intent and perilously interferes with the government's ability to administer these massive nationwide programs. Private suits also risk the imposition of conflicting obligations and of unjustified burdens on drug manufacturers.

Third, the court of appeals' recognition of a private right of action under the common law jettisons the bedrock principles that "[t]here is no general federal common law," *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), and that only Congress can create private rights of action to enforce a statute, *e.g.*, *Alexander v. Sandoval*, 532 U.S. 275 (2001). In striking disregard of those precedents, the court of appeals concluded that the burden was on *Congress* to *abrogate* a pre-existing federal common law right of action for breach of contract. The Ninth Circuit's invocation of federal common law to confer a right of action where none exists by statute reflects a serious judicial usurpation of legislative power.

## I. THE NINTH CIRCUIT'S DECISION DEEPENS AN ENTRENCHED CIRCUIT CONFLICT

In holding that federal common law authorizes a cause of action to enforce a statutory requirement, the Ninth Circuit deepened a conflict in the circuits on the question of whether the common law may ever

trump the absence of an express or implied private right of action. Three courts of appeals, in sharp contrast to the Ninth Circuit, have answered that question in the negative, holding that judge-made law cannot provide a right of action that Congress did not authorize. A 5-3 circuit split has developed over decades and is firmly entrenched. This case is also a perfect vehicle to resolve an issue that recurs routinely under a vast variety of federal programs administered through contracts between federal agencies and private parties.

### A. The Circuits Are Deeply Divided Over The Validity Of A Common Law Third-Party Beneficiary Claim To Enforce Statutory Mandates Incorporated Into A Contract

1. The Ninth Circuit's holding that federal common law forms the basis of a private right of action to enforce an Act of Congress squarely conflicts with the decisions of three circuits that have rejected the validity of such an action. The Second Circuit in *Grochowski v. Phoenix Construction*, 318 F.3d 80 (2d Cir. 2003), held that where a federal statute provides no private right of action, it follows *a fortiori* that a third party cannot enforce the statute by asserting a common law claim as an intended beneficiary of a contract embodying the statutory requirement. *Id.* at 86. In *Grochowski*, workers sued building contractors operating federally funded construction contracts for the contractors' alleged failure to pay the wages required by the Davis-Bacon Act. The court of appeals held that circuit precedent establishing the absence of a private right of action under Davis-Bacon was likewise dispositive of the workers' common law claims that they were third-party beneficiaries of the contract, which had incorporated the Act's wage requirements. *Id.*

In contrast with the Ninth Circuit here, the Second Circuit reasoned that, when there is no statutory private right of action, such a right cannot be pursued simply by recasting it as a contract claim under the common law. *Id.* at 85-86. The court explained that common law claims "are indirect attempts at privately enforcing the prevailing wage schedules contained in the [Act]," and would interfere with congressional intent "to the same extent as would a cause of action directly under the statute." *Id.* at 86 (internal quotation marks omitted). Thus, the court concluded that where "no private right of action exists under the relevant statute," a plaintiff's efforts to bring common law claims "are clearly an impermissible 'end run' around the [Act]." *Id.*

The Sixth Circuit followed the same rule in *Hoopes v. Equifax, Inc.*, 611 F.2d 134 (6th Cir. 1979). In that case, a discharged employee sued his former employer for disability discrimination in violation of the Rehabilitation Act, arguing that he was "entitled to challenge his dismissal because he was a third party beneficiary under a contract between his employer and the United States Government." *Id.* at 135. The Sixth Circuit affirmed summary judgment against the employee, explaining that the Act "does not authorize a private cause of action in the courts." *Id.*

The Tenth Circuit followed *Hoopes* in *Hodges v. The Atchison, Topeka & Santa Fe Railway Co.*, 728 F.2d 414 (10th Cir. 1984) In *Hodges*, a discharged railroad worker sued his former employer claiming wrongful discharge, also in violation of the Rehabilitation Act, arguing both that the statute contains an implied private right of action, *id.* at 415, and that he was "a third-party beneficiary" to the railroad's "federal contracts which prohibit discrimination against the handicapped, pursuant to"

the Act, *id.* at 416. The Tenth Circuit analyzed the issue under *Cort v. Ash*, 422 U.S. 66 (1975), and held that "neither the legislative history nor the Act in general" could support a private right of action. *Hodges*, 728 F.2d at 415. The court disallowed the "third-party beneficiary" claim for the same reasons, stating that "[t]his is but another aspect of the implied right of action argument." *Id.* at 416 (citing the Sixth Circuit's decision in *Hoopes*).

2. Departing from those holdings are the decisions of five circuits, including the Ninth Circuit, that have held that, notwithstanding the absence of an implied right of action, a statutory requirement embodied in a contract may be enforced by a "third party beneficiary" claim for breach of contract. For instance, in *Dewakuku v. Martinez*, 271 F.3d 1031 (Fed. Cir. 2001), the Federal Circuit entertained a third-party beneficiary common law claim for breach of contract even though the court held that there was no private right of action under the statute at issue, the Indian Housing Act of 1988. *Id.* at 1037. The court separately examined the common law question because the statutory requirement sought to be enforced had been incorporated into a contract with the government. *Id.* at 1040-41. The court held that the "test for intended third party beneficiary status is whether the contract reflects the intent of the parties to the contract to benefit the third party." *Id.* at 1041.

Similarly, the Seventh Circuit in *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir. 1985), after noting that "no private right of action arises under Section 503" of the Rehabilitation Act, nonetheless held that federal common law could supply a cause of action because the two doctrines were distinct. *Id.* at 1478. The court reasoned that although congressional intent controls the question of a statutory private right of action, a common law

claim rests on "whether the parties" to the contract "intended to confer an actionable right." *Id.* at 1478-79. Other circuits have similarly held that a third party beneficiary claim may be pursued if the "common law" elements are met, even in the absence of an implied right of action. *Nguyen v. The U.S. Catholic Conf.*, 719 F.2d 52 (3d Cir. 1983) (Refugee Assistance Act of 1962); *Perry v. Housing Auth. of Charleston*, 664 F.2d 1210, 1217-18 (4th Cir. 1981) (Housing Act of 1937, 42 U.S.C. § 1437, *et seq.*); *Falzarano v. United States*, 607 F.2d 506, 511 (1st Cir. 1979) (National Housing Act, 12 U.S.C. § 1715L).

### B. The Circuit Split Warrants This Court's Intervention

1. This Court's intervention is warranted to resolve the circuit conflict and bring uniformity to an important and recurring area of federal law. There are few questions of federal law as worthy of this Court's attention as the power of federal courts to create causes of action from whole cloth without authority from Congress. The court of appeals' decisions that have confronted the question have arisen under a variety of different public welfare programs that are administered through contracts incorporating statutory requirements. *Supra*, pp. 14-17. And despite the recurring nature of the issue under a wide variety of federal assistance programs, this Court has never addressed the precise issue of whether a common law breach of contract claim exists to enforce an Act of Congress that is implemented through contracts even where the Act does not contain an implied right of action.

"Because of the frequency with which the government employs contracts as instruments of federal policy, recent years have been marked by a wave of cases involving third-party beneficiary claims under contracts with agencies of the federal government." Note: *Who's Watching the Watchdogs?*

103 Colum. L. Rev. 893, 918 (2003). Third party beneficiary claims frequently arise because they serve as a means to evade this Court's limitations on the ability of courts to imply causes of action. As one commentator has observed, "a third party beneficiary claim is more likely to prevail than an [implied right of] action on the statute." Anthony Jon Waters, *The Property in the Promise: A Study of the Third Party Beneficiary Rule*, 98 HARV. L. REV. 1109, 1176 and 1178 (1985); *see also* Note: *Third Party Beneficiary & Implied Right of Action Analysis: The Fiction of One Governmental Intent*, 94 YALE L.J. 875, 875 (1985) (explaining that because of "the Supreme Court's increasingly restrictive view of implied rights of action," "in recent years the number of third-party claims arising from welfare-related public contracts has grown significantly" (footnote omitted)); Note: *The Power Behind the Promise: Enforcing No Child Left Behind to Improve Education*, 45 B.C. L. REV. 667 (2004) (urging litigants to sue as third party beneficiaries to enforce the No Child Left Behind Act of 2001).

The issue thus regularly arises in district courts under numerous federal laws. *See, e.g., D.G. v. Henry*, 594 F. Supp. 2d 1273, 1281 (N.D. Okla 2009) (Adoption Assistance and Child Welfare Act of 1980); *Rogers v. U.S. Army*, NO. H-06-1389, 2007 U.S. Dist. LEXIS 30056, at *38 (S.D. Tex. Apr. 23, 2007) (Davis-Bacon Act); *Sabeta v. Baptist Hosp. of Miami, Inc.*, 410 F. Supp. 2d 1224, 1233-34 (S.D. Fla 2005) (Section 501(c)(3) of the tax code); *Charlie & Nadine H. v. Whitman*, 83 F. Supp. 2d 476, 502 (D.N.J. 2000) (Adoption Assistance Act and Child Abuse Prevention and Treatment Act); *Brug v. National Coal. for the Homeless*, 45 F. Supp. 2d 33, 41 (D.D.C. 1999) (affirmative action guidelines for government contractors); *In re Lake States Commodities, Inc.*, 936 F. Supp. 1461, 1470 & n.13 (N.D. Ill 1996) (Commodities Exchange Act § 13(a)).

Finally, in addition to the Medicaid drug rebate and 340B ceiling price programs, other important health care programs are administered through contract mechanisms. *See, e.g.*, 38 U.S.C. § 8126(a) (Department of Veterans Affairs health care program); 10 U.S.C. § 1074g(f) (DoD "TRICARE" retail pharmacy benefit); 42 U.S.C. § 1395w-101(a) (Medicare outpatient prescription drug benefit "coverage gap rebate program," created by Patient Protection and Affordable Care Act).

2. The conflict in the circuits is mature and ripe for this Court's review. The Second, Sixth, and Tenth Circuits have had no difficulty rejecting a common law claim as the source of a cause of action that Congress itself did not provide. The First, Third, Fourth, Ninth, and Federal Circuits, however, have held that the federal common law, independent of a statute, may confer a private right of action. Indeed, in *D'Amato*, the Seventh Circuit criticized the Sixth Circuit's decision in *Hoopes* for "failing" "to distinguish between" the "determination of whether a private right of action arises directly under the statute" and whether a common law claim may be brought under a "third party beneficiary theory." 760 F.2d at 1478 n.3 & n.4.

Moreover, although the Ninth Circuit attempted to distinguish the Second Circuit's decision in *Grochowski*, its reasoning actually reinforces the fundamental division in the circuits. The Ninth Circuit reasoned that there was no basis for a common law remedy in *Grochowski* because the government had promulgated regulations creating administrative remedies for violations of the Davis Bacon Act. App., *infra*, 24a-27a. By contrast, because 340B entities had no statutory or administrative remedies to invoke against drug manufacturers, the Ninth Circuit deemed that it had the authority to create a judicial remedy that would

not be adding a remedy over and above what the statute provided. *Id.*

The court's analysis completely misses the point of *Grochowski* that recognition of a common law claim is an "end run" around Congress's decision not to provide a private right of action. The existence of administrative remedies may be relevant to whether there is an implied right of action in the first place, but the absence of an implied right of action ends the inquiry, including any examination of whether a judicial remedy would supplant or supplement an administrative remedy authorized by Congress. The Ninth Circuit thus seriously erred in relying on the absence of an administrative remedy as a basis for imposing a judicial remedy. Creating a judicial remedy where Congress provided none condones precisely the end-run rejected in *Grochowski*. Because only this Court can resolve the fundamental division in the circuits on the threshold propriety of a common law cause of action in the absence of an express or implied right under the statute, this Court's intervention is warranted.

3. This case represents an excellent vehicle for this Court to resolve the conflict in the circuits. The issue on which the circuits are divided is cleanly presented in this case, and there is no need for further factual development. Moreover, no proceedings on remand would bear on the Court's disposition of the case. Although the court of appeals left open the possibility that deferral to the Secretary might be warranted under the doctrine of primary jurisdiction, App., *infra*, 27a-29a, deferral would not lead to the dismissal of the suit, *i.e.*, the result that would be compelled under the rule adopted by the Second, Sixth, and Tenth Circuits. Moreover, the court of appeals' decision announces a broad rule with far-reaching implications and already has caused immediate harm in this case. *See infra*, pp.

23-24. There is no reason for this Court to wait to resolve a recurring and important issue that has long divided the circuits.

## II. THE NINTH CIRCUIT'S DECISION SERIOUSLY DISRUPTS THE MEDICAID DRUG REBATE AND 340B CEILING PRICE PROGRAMS

### A. The Court of Appeals' Recognition Of A Private Right Of Action Under The Statutory Drug Pricing Provisions Warrants Review

1. The Ninth Circuit's recognition of a private right of action to enforce both the Medicaid Act and 340B Act pricing provisions warrants this Court's review. Both the Medicaid drug rebate program and the Section 340B ceiling price program are administered though contracts incorporating the statutory requirement that drug manufacturers calculate and accurately report to the Secretary AMP and Best Price information. Whether there is a common law private right of action against drug manufacturers to challenge their drug pricing obligations under two major health care Acts of Congress is an issue of abiding national importance.

The Ninth Circuit's holding directly impacts a government financial assistance program that is massive in size and scope. In fiscal year 2002 alone, Medicaid drug expenditures totaled $29.3 billion. In 2002, drug manufacturers paid Medicaid rebates to States totaling $5.6 billion. *See supra*, n.1. In 2005, 340B entities spent $4 billion on covered outpatient drugs. *See supra*, n.2. More than 800 drug manufacturers report AMP and Best Price data for

over 35,000 pharmaceuticals. *See supra*, nn. 1 & 3. Over 14,500 entities are currently covered by Section 340B, over 2,700 of which are located in the States within the Ninth Circuit alone. *See supra*, n.3.[5]

Moreover, the recent health care reform legislation significantly expands the categories of 340B entities, and thus the potential plaintiffs that may file suit under the rule of the Ninth Circuit. *See* Patient Protection & Affordable Care Act, Pub. L. No. 111-148, § 7101, 124 Stat. 119 (2010) (expanding the categories of eligible entities under the 340B Program to include certain children's hospitals, free standing cancer hospitals, critical access hospitals, rural referral centers, and sole community hospitals).

2. Given the sheer size and breadth of the Medicaid rebate program for which AMPs and Best Prices are calculated and reported, as well as the 340B ceiling price program in which AMPs and Best Prices are used to set ceiling prices, plaintiffs suing under a private right of action could seek to impose massive liability and burdens on drug manufacturers. This class action lawsuit is not an isolated incident. *See Central Ala. Comprehensive Healthcare, Inc. v. Aventis Pharm., Inc.*, 427 F. Supp. 2d 1129 (M.D. Ala. 2006) (putative nationwide class

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[5] Health Resources and Services Administration, Office of Pharmacy Affairs Database, http://opanet.hrsa.gov/opa/Report/DailyReport.aspx (last visited Apr. 4, 2010); Health Resources and Services Administration, Office of Pharmacy Affairs Database, Covered Entity Data Extract, http://opanet.hrsa.gov/opa/CE/CEExtract.aspx (last visited Apr. 4, 2010).

action under Section 340B Program); *In re Pharm. Ind. Average Wholesale Price Litig.*, MDL No. 1456, 2007 WL 1051642 (D. Mass. Apr. 2, 2007) (suit by State and 42 counties as third party beneficiaries under rebate program); *In re Pharm. Ind. Average Wholesale Price Litig.*, 339 F. Supp. 2d 165 (D. Mass. 2004) (suit by county as third party beneficiary under rebate program). Forcing drug companies to defend such suits is wholly unwarranted, absent clear evidence that Congress authorized a cause of action under either Act.

Indeed, the mere pendency of a private party suit seeking to enforce statutory drug pricing requirements imposes enormous and unjustified burdens on drug manufacturers. For example, the suit here alleges that petitioners over a nine-year period miscalculated the AMP and the Best Price of covered outpatient drugs, causing 340B entities in California to pay a higher price for covered drugs than warranted under the 340B drug ceiling price program. The Medicaid Act requires manufacturers to calculate the AMP and Best Price based on *nationwide* sales transactions to all eligible purchasers. 42 U.S.C. § 1396r-8.

Petitioners in this case have thus been ordered to produce confidential and sensitive drug pricing and sales information on a national basis for hundreds of millions of drug sale transactions. App., *infra*, 74a-77a. The breadth and quantity of that information is breathtaking. For petitioner GlaxoSmithKline, for instance, the suit covers "more than 100 million [computer] data records per quarter" that sort and analyze data for the company's AMP and Best Price

calculations. Declaration of David Brown (Mar. 11, 2010) ¶ 9. That size and scope is typical for other manufacturers as well. *See, e.g.*, Declaration of Paul Le Compte ¶ 5 (Mar. 11, 2010) ("approximately 150 million sales records" for Pfizer); Declaration of Kathleen Dynan Black ¶ 8 (Mar. 11, 2010) ("over 30 million sales transactions" for Wyeth). The pendency of any litigation is a serious burden to any defendant, but this particular litigation, if allowed to proceed, involves burdens that vastly exceed the norm and thus makes immediate intervention by this Court particularly warranted.

### B. The Ninth Circuit's Decision Disrupts Both The Medicaid Drug Rebate and 340B Ceiling Price Programs

1. The calculation of AMP and Best Price used to determine Medicaid rebates and 340B ceiling prices involves difficult and exceedingly complex questions of statutory interpretation, application, and calculation. *See* Gov't Br., 2009 WL 4089524, at *6. While the Secretary has issued approximately 80 informal guidance "releases" and regulations concerning drug price regulation, she has yet to resolve many outstanding interpretive and calculation issues. That regime has resulted in manufacturers' employing varying calculation methods. *Id.* The government's administration and enforcement of the statutory scheme should not be second-guessed by courts and juries deciding private suits challenging drug manufacturers' calculations of the AMP and Best Price for covered drugs. As the agency has concluded, "[a]llowing plaintiffs challenge would undermine HHS's role and

improperly shift the yardstick by which manufacturers' reports are judged." *Id.* at *9.

The damage wrought by the court of appeals' decision extends to the Medicaid Drug Rebate Program as well as the Section 340B Program. As discussed, the Section 340B Program expressly incorporates the drug pricing provisions of the Medicaid Drug Rebate Program. 42 U.S.C. § 256b(a) (incorporating by reference 42 U.S.C. 1396r-8). "[D]isputes over AMP and Best price are challenges to prices reported as part of the Medicaid Rebate Program." Gov't Br., 2009 WL 4089524, at *9. The government thus has concluded that a private right of action would "squarely implicate[] [HHS's] oversight of" Medicaid and would disrupt the operation of "*both* programs." *Id.* at *9, *11 (emphasis in original).

If not reversed, the Ninth Circuit's recognition of a private right of action seriously threatens to impose conflicting obligations on drug manufacturers under bo. . the Medicaid drug rebate and 340B ceiling price programs, contrary to the exclusive authority Congress conferred on the government "to resolve issues for both programs at once." *Id.* at *15. The government explained to the Ninth Circuit that 340B entities have the incentive to allege that manufacturers overstated their AMP calculations, which, if reduced, would likely reduce 340B ceiling prices (to the advantage of the plaintiffs in this litigation)—but would also reduce the comparatively much larger Medicaid rebate payments to States.

Thus, States, under the Medicaid program, have the opposite incentive—to maintain the higher reported AMPs, which would increase the rebates the States receive:

> The problem is that, in some circumstances, challenges to an AMP calculation can have opposite effects on 340B entities and state Medicaid plans. In the 340B Program, a drug's ceiling price will be AMP minus [the unit rebate amount], giving covered entities an incentive to argue that AMP should be as low as possible—a lower AMP generally means a lower ceiling price. On the other hand, because states' rebates will often be a defined percentage of AMP . . . , states often have an incentive to argue that AMP figures should be higher.

*Id.* at *15. "Accordingly, if both 340B entities and states can bring separate suits over AMP calculations, there is a real danger that manufacturers could be subject to inconsistent obligations." *Id.* That risk is wholly unjustified when Congress did not intend to confer any private right of action to enforce the statutory scheme.

## III. THE NINTH CIRCUIT'S DISREGARD OF THIS COURT'S JURISPRUDENCE WARRANTS REVIEW

The court of appeals' decision is patently erroneous. This class action seeks to enforce *statutory* requirements, *i.e.*, the drug pricing statutory formula for determining the AMP and Best Price under the Medicaid Act's drug rebate program

and the 340B Act's ceiling prices. The contract merely incorporates the Medicaid Act and 340B Act drug pricing obligations, App., *infra*, 170a-71a (PPA ¶¶ II(a)-(d)), and does not impose any additional pricing obligations. The County concedes that the breach of contract claim hinges on the allegation that petitioners charged more than the ceiling price permitted by Congress. Appellants' C.A. Br. 6 (Mar. 16, 2009); Third Am. Compl. (Dec. 23, 2008). Neither the Medicaid Act nor the 340B Act expressly or impliedly confers a private right of action. The court of appeals' erroneous creation of a new right of action under the guise of enforcing a contract merits this Court's correction.

### A. The Federal Common Law Cannot Create A Private Right Of Action To Enforce A Statutory Requirement

1. "There is no general federal common law." *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). "Federal courts, unlike state courts, are not general common-law courts and do not possess a general power to develop and apply their own rules of decision." *City of Milwaukee v. Illinois*, 451 U.S. 304, 312 (1981); *see Texas Indus., Inc. v. Radcliff Mat'ls, Inc.*, 451 U.S. 630, 640 (1981). And, to the extent that Congress has authorized courts to develop federal common law, such as under ERISA or the Sherman Act, it is elementary that federal common law is "subject to the paramount authority of Congress." *Northwest Airlines, Inc. v. Transport Workers Union of Am.*, 451 U.S. 77, 95 (1981).

Accordingly, this Court has repeatedly rejected attempts to graft common law rights and remedies onto federal statutes that do not provide them. For example, in *Mertens v. Hewitt Associates*, 508 U.S. 248 (1993), the Court held that federal common law could not form the basis of ERISA liability for non-fiduciaries because the Act did not affirmatively

authorize such a suit. *Id.* at 255 & n.5. Similarly, in *Texas Industries*, the Court rejected a common law claim for contribution under the federal antitrust statutes because the authority to create such a claim was within the exclusive province of Congress. 451 U.S. at 646.

2. The court of appeals' decision violates those settled principles. Indeed, the court concluded that the burden was on Congress to *displace* a general federal common law cause of action. The court thus reasoned that "§ 256 *does not abrogate* the cause of action ordinarily provided by the federal common law of contracts." App., *infra*, 24a n.16 (emphasis added). There is, however, no free-standing cause of action under the federal common law in favor of 340B entities that Congress must "abrogate." Rather, Congress must affirmatively authorize the cause of action.

That conclusion is not altered by the fact that the agreements at issue here "shall be *construed* in accordance with Federal common law." App., *infra*, 180a (¶ VII(g)) (emphasis added). All that provision does is to identify federal common law, as opposed to that of any specific State, as the source of law for interpretation of the document in the event a term is disputed by the parties to the agreement. It is well settled that federal common law principles govern the contractual obligations of the United States. *E.g., Mobil Oil Expl. & Producing Se., Inc. v. United States*, 530 U.S. 604 (2000).[6]

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[6] The Ninth Circuit in a footnote stated that the court was not resolving "whether federal or state law creates the cause of action underlying [the County's] contract claim." App., *infra*, 8a n.5. The PPA by its terms, however, is governed by federal

Neither a government contract nor common law principles governing the parties' contractual obligations, however, may form the basis of a private right of action to enforce an act of Congress. *Erie* long ago established that federal common law is not a grant of judicial power to create new substantive rights. As the Court has emphasized, "recognition of any private right of action for violating a federal statute must ultimately rest on congressional intent to provide a private remedy." *Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1102 (1991); *see Wheeldin v. Wheeler*, 373 U.S. 647, 651 (1963) ("As respects the creation by the federal courts of common-law rights, it is perhaps needless to state that we are not in the free-wheeling days antedating *Erie*."). Likewise, any right by private parties to enforce the manufacturers' obligations under the Act's drug pricing provisions must stem from congressional authorization.

That principle cannot be circumvented simply by dressing the same claim up in breach of contract garb. For instance, in *United States v. Erika, Inc.*, 456 U.S. 201, 206-08 (1982), this Court held that the structure of the Medicare Act reflected an implied legislative intent to preclude judicial review of determinations by private insurance carriers of the amount of benefits payable under Part B of the

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common law, *id.* at 180a (¶ VII(g)), and the court of appeals repeatedly invoked "*federal* common law" to recognize a right of action by Section 340B covered entities. *See, e.g.*, *id.* at 10a, 22a, 26a, 27a (emphasis added). The County also based its breach of contract claim on federal common law. *E.g.*, Appellants C.A. Br. 3, (Mar. 16, 2009); Appellants C.A. Br. 3, 14, 16 (Nov. 22, 2006).

Medicare program, 42 U.S.C. § 1395j *et seq.* (1976). The Court rejected the plaintiff's claim that, separate from any rights arising under the Act, a Medicare provider derived a substantive right to seek review of the carrier's determination "from an implied-in-fact contract with the United States or as a third-party beneficiary to [the carrier's] contract with the United States." 456 U.S. at 211 n.14.

This Court explained that those "arguments fail because any such contracts with the United States necessarily would include the statutory preclusion of review of hearing officers' determinations regarding the amount of Part B benefits." *Id.* The Court reasoned that the judicial task was "at an end" because Congress did not intend to provide for judicial review of the carrier's determination. The same principle here precludes 340B entities from using a pleading device to evade the absence of an implied right of action to enforce the 340B Act. *See Tenet v. Doe*, 544 U.S. 1, 8 (2005) (holding that preclusion of judicial review under *Totten v. United States*, 92 U.S. 105 (1876) applies "[n]o matter the clothing in which [plaintiffs] dress their claims").

This Court's decision in *Alexander v. Sandoval*, 532 U.S. 275 (2001), further establishes that even an affirmative intent by the Executive Branch to create substantive rights cannot trump the absence of an implied right of action. The Court in *Sandoval* squarely rejected the principle that "language in a [government] regulation can conjure up a private cause of action that has not been authorized by Congress." *Id.* at 291. The Court explained that "[a]gencies may play the sorcerer's apprentice, but not the sorcerer himself." *Id.* That holding forecloses

any argument that the Secretary, by executing the PPA, could have conferred a private right of action.

### B. The Court Of Appeals' Decision Violates The Court's Implied Right Of Action And Spending Clause Jurisprudence

1. The Ninth Circuit's recognition of a private right of action under the common law turns this Court's modern jurisprudence concerning such a right on its head. The premise of an implied right of action is that *Congress* intended to confer a private right of action but failed to say so expressly. *Thompson v. Thompson*, 484 U.S. 174, 179 (1988); *Cannon v. University of Chicago*, 441 U.S. 677, 688 (1979); *Cort v. Ash*, 422 U.S. 66 (1975). Absent congressional intent, "a cause of action does not exist and courts may not create one." *Sandoval*, 532 U.S. at 286-87. Thus, a court must always "first determine whether Congress *intended to create a federal right*." *Gonzaga Univ. v. Doe*, 536 U.S. 273, 283 (2002); *see Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 13 (1981) ("The key to the inquiry is the intent of the Legislature."); *California v. Sierra Club*, 451 U.S. 287, 293 (1981) ("[T]he ultimate issue is whether Congress intended to create a private right of action.").

Congress's exclusive authority to create new federal rights is rooted in the separation of powers: "In the absence of congressional intent, the Judiciary's recognition of an implied private right of action necessarily extends its authority to embrace a dispute Congress has not assigned it to resolve." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008) (internal quotation marks omitted); *accord Gonzaga Univ.*, 536 U.S. at 285-86; *Northwest Airlines*, 451 U.S. at 94.

The Ninth Circuit's decision eviscerates the foundational underpinnings of those precedents. The court of appeals expressly assumed the absence of a private right of action by 340B entities under the statute, while simultaneously invoking federal common law to confer that right anyway. App., *infra*, 8a, 22a n.15, 29a. The Ninth Circuit reasoned that a private right of action furthered congressional intent because "[f]ederal common law contract remedies are one way of ensuring that drug companies comply with their obligations under the program and provide those discounts." *Id.* at 27a. It further asserted that it "'seemed more sensible' to permit third parties to sue as intended beneficiaries than to 'place the entire burden of enforcement' on the government." *Id.* (quoting *Price v. Pierce*, 823 F.2d 1114, 1119-21 (7th Cir. 1987)). Far from furthering congressional intent, however, the decision patently subverts that intent by giving 340B entities a private right of action to enforce the very statutory requirements that Congress concededly did *not* intend to be enforced by private parties.

2. The Ninth Circuit's decision also flouts this Court's precedents under the Spending Clause. The Medicaid drug rebate and Section 340B ceiling price programs are Spending Clause enactments. As discussed, the Acts require drug manufacturers to enter into contracts under both the drug rebate and ceiling price programs as a condition of federal financial participation for outpatient drugs covered under State Medicaid plans. *Supra*, pp. 7-8; *see* Joint Explanatory Statement on H.R. 5193, 138 Cong. Rec. S17890 (1992) (explaining that 42 U.S.C. § 256b makes the "use of federal matching funds for payment for a covered outpatient drug [by State Medicaid programs] * * * contingent on * * * a manufacturer's entering into [ ] an agreement * * * under which the manufacturer agrees to provide rebates or discounts to" covered entities).

This Court has repeatedly made clear that intended beneficiaries of Spending Clause legislation may not sue to enforce statutory requirements that are a condition of federal funds unless there is an express or implied right of action under the statute. *See, e.g., Sandoval*, 532 U.S. at 286; *Franklin v. Gwinnett County Pub. Sch.*, 503 U.S. 60 (1992); *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1 (1981). Indeed, an implied right of action alone is insufficient. Because Spending Clause legislation "is much in the nature of a contract . . . if Congress intends to impose a condition on the grant of federal monies, it must do so unambiguously." *Pennhurst*, 451 U.S. at 17; *see, e.g., Barnes v. Gorman*, 536 U.S. 181, 186 (2002); *Davis v. Monroe County Bd. of Educ.*, 526 U.S. 629, 640 (1999).

There is no implied right of action to enforce the drug pricing provisions under the 340B Act, and drug manufacturers accordingly had no warning that they could be subject to class action suits by private parties to enforce those provisions. Indeed, as the government explained in its amicus brief to the Ninth Circuit, the agency too "never imagined that a 340B entity could bring a third-party beneficiary lawsuit." Gov't Br., 2009 WL 4089524, at *12. In short, as the agency stated, permitting this challenge would "confer . . . rights never intended by the PPA signatories." *Id.* at *9. The court of appeals' decision casts aside decades of settled doctrine and paves the way for class action suits against drug manufacturers when neither the government nor the manufacturers could have possibly anticipated that result.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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APRIL 20, 2010

# APPENDIX

# APPENDIX A — ORDER AND OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT FILED DECEMBER 9, 2009

## UNITED STATES COURT OF APPEALS
## NINTH CIRCUIT

**No. 06-16471.**

COUNTY OF SANTA CLARA,

Plaintiff-Appellant,

v.

ASTRA USA, INC.; AstraZeneca Pharmaceuticals LP; Aventis Pharmaceuticals, Inc.; Bayer Corporation; Bristol-Myers Squibb Company; Pfizer, Inc.; Schering-Plough Corporation Tap Pharmaceutical Products, Inc.; Zenecca Inc.; ZLB Behring LLC; SmithKline Beecham Corporation; SmithKline Beecham Corporation, dba GlaxoSmithKline; Wyeth, Inc.; Wyeth Pharmaceuticals, Inc.,

Defendants-Appellees.

Argued and Submitted March 11, 2008.
Filed Dec. 9, 2009.

*Appendix A*

Appeal from the United States District Court for the Northern District of California, William H. Alsup, District Judge, Presiding. D.C. No. CV-05-03740-WHA.

Before: STEPHEN REINHARDT, BARRY G. SILVERMAN and RAYMOND C. FISHER, Circuit Judges.*

ORDER AND OPINION**

**ORDER**

The mandate issued September 18, 2008, is hereby recalled.

The opinion filed August 27, 2008, *see County of Santa Clara v. Astra USA, Inc.*, 540 F.3d 1094 (9th Cir.2008), is withdrawn. A superseding opinion will be filed concurrently with this order. Petitions for rehearing or petitions for rehearing en banc may be filed.

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* After the original opinion was published, Judge Silverman was substituted for the late Judge Melvin Brunetti.

** After we published an opinion in this case and remanded it to the district court, the district court certified a subsequent immediate appeal, No. 09-15216, under 28 U.S.C. § 1292(b) so that we could clarify a statement in the opinion that had an unexpected bearing on a discovery issue. Because reconsideration of that statement could have also required us to revisit the primary jurisdiction issue, we invited the Secretary of Health and Human Services to file an amicus brief. We now withdraw our earlier opinion and replace it with this opinion.

*Appendix A*

## OPINION

FISHER, Circuit Judge:

Certain federally funded medical clinics-so-called "Section 340B covered entities"-are able to purchase prescription drugs at a discount from drug manufacturers under a standardized agreement between the federal government and the drug companies. During 2003, for example, these covered entities spent $3.4 billion on outpatient prescription drugs. They claim in this lawsuit that they have been overcharged for those drugs in violation of pharmaceutical pricing agreements between the Secretary of Health and Human Services ("Secretary") and the drug manufacturer defendants-appellees ("Manufacturers"). Applying the federal common law of contracts, we hold that the covered entities are intended direct beneficiaries of these agreements and thus have the right to enforce the agreements' discount provisions against the Manufacturers and sue them for reimbursement of excess payments. We have jurisdiction under 28 U.S.C. § 1291, and reverse the district court's dismissal of the complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim.

*Appendix A*

## BACKGROUND[1]

In part to "enable . . . certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients," *see* H.R.Rep. No. 102-384(II), at 7 (1992), Congress enacted Section 602 of the Veterans Health Care Act of 1992, Pub.L. No. 102-585, 106 Stat. 4943, 4967. That provision, entitled "Limitations on Prices of Drugs Purchased by Covered Entities," requires the Secretary of Health and Human Services to:

> enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug under [§ 1396r-8(k)(1)] in the preceding calendar quarter, reduced by [a] rebate percentage described in [§ 256b(a)(2)].

42 U.S.C. § 256b(a)(1).[2] This drug discounting program is commonly known as the "Section 340B program,"

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1. Because this is an appeal from an order granting a motion to dismiss, we accept all facts alleged as true and construe them in the light most favorable to the plaintiff. *See Karam v. City of Burbank*, 352 F.3d 1188, 1192 (9th Cir.2003).

2. Hereinafter, all citations are to Title 42 of the United States Code unless otherwise noted.

tracing back to its original location within the Public Health Service Act.[3] The program is managed by the Health Resources and Services Administration ("HRSA"), a subdivision of the Department of Health and Human Services ("DHHS"). *See* Statement of Organizations, Functions, and Delegations of Authority, 58 Fed.Reg. 19,137-02 (Apr. 12, 1993). In accordance with statute, the Secretary entered into a standard Pharmaceutical Pricing Agreement ("PPA") with each of the Manufacturers.

One of the Manufacturers' principal obligations under the PPA is "to charge covered entities a price . . . that does not exceed . . . the [average manufacturer price] for the covered outpatient drug reported . . . . to the Secretary in accordance with the Manufacturer's responsibilities under [§ 1396r-8(b)(3)], reduced by the rebate percentage." *See* PPA § II(a).[4] The PPA defines "average manufacturer price," "covered entity," "manufacturer" and "rebate percentage" to "have the meanings specified in [§§ 256b and 1396r-8], as interpreted and applied herein."

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3. Section 602 of the Veterans Health Care Act of 1992 added a new Section 340B to Part D of Title III of the Public Health Service Act. *See* 106 Stat. at 4967. The Public Health Service Act is itself codified at Chapter 6A of Title 42 of the United States Code. *See* National Institutes of Health Revitalization Act of 1993 § 2008(i)(1)-(2), Pub.L. No. 103-43, 107 Stat. 122, 212-13.

4. The PPA establishes different discounts for other classes of drugs that are not relevant here. *See* PPA §§ II(b)-(c).

*See* PPA §§ I(a)-(*o*). Also known as the "ceiling price," the maximum price that covered entities may be charged under the PPA is calculated using proprietary sales and pricing information the Manufacturers disclose only to the Secretary.

The genesis of the present appeal is a putative class action filed in California state court by the county of Santa Clara and a number of county-operated medical facilities ("Santa Clara"), which are covered entities within the meaning of § 256b(a)(4) and PPA § I(e). Relying chiefly on reports published by DHHS's Office of the Inspector General ("OIG"), Santa Clara alleged that the Manufacturers have systematically overcharged its medical facilities, and all similarly situated covered entities, for covered drugs. OIG's March 2003 report estimated that overcharges during the one-year period ending September 1999 totaled $6.1 million. Its June 2004 report, which was withdrawn in October 2004 because of "problems with the underlying data," concluded that covered entities overpaid $41.1 million in the month of September 2002. In October 2005, OIG confirmed that its June 2004 calculation was erroneous because the Centers for Medicare and Medicaid Services had provided it with comparison "ceiling prices from the wrong timeframe." OIG did not retreat, however, from its other, more general findings that HRSA was not adequately overseeing the Section 340B program and that "HRSA lacks the oversight mechanisms and authority to ensure that [covered] entities pay at or below the . . . ceiling price." The October 2005 report also "introduce[d] new

concerns" that "systemic problems with the accuracy and reliability" of the government's pricing data could interfere with HRSA's ability to monitor the Section 340B program. Finally, a 2006 OIG report estimated that covered entities overpaid $3.9 million in June 2005 alone.

Santa Clara initially brought claims under the California False Claims Act and California Unfair Competition Law in state court. After the Manufacturers removed the action to federal district court, Santa Clara amended its complaint for the first time. The district court granted the Manufacturers' motion to dismiss, but with leave to amend. Santa Clara's second amended complaint, now including claims for breach of the PPA, breach of the implied covenant of good faith and fair dealing, negligence and quantum meruit, fared no better than the first. The district court granted the Manufacturers' second motion to dismiss and denied as futile Santa Clara's subsequent motion for leave to file a third amended complaint. Santa Clara appeals only the district court's rejection of its PPA breach of contract claim on a third party beneficiary theory.

## STANDARD OF REVIEW

"We review de novo the district court's dismissal of a complaint for failure to state a claim under Rule 12(b)(6)." *Vasquez v. Los Angeles County*, 487 F.3d 1246, 1249 (9th Cir.2007). The interpretation of a contract is a mixed question of law and fact that we review de novo. *Klamath Water Users Protective Ass'n v. Patterson*, 204 F.3d 1206, 1210 (9th Cir.1999).

*Appendix A*

## DISCUSSION

We agree with Santa Clara that covered entities are intended direct beneficiaries of the PPA and have the right as third parties to bring claims for breach of that contract. We also conclude that allowing such suits under the PPA is consistent with Congress' intent in enacting the Section 340B program, even though the statute itself does not create a federal private cause of action. Finally, we reject the Manufacturers' argument that primary jurisdiction is appropriate.

### I.

Federal law controls the interpretation of the PPA, which is a "contract[ ] entered into pursuant to federal law and to which the government is a party," *Smith v. Cent. Ariz. Water Conservation Dist.*, 418 F.3d 1028, 1034 (9th Cir.2005), and which expressly provides that it "shall be construed in accordance with Federal common law," *see* PPA § VII(g).[5] "For guidance, we may

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5. "[F]ederal jurisdiction cannot be created by contract," of course, and we have an independent obligation to scrutinize our jurisdiction. *ARCO Envtl. Remediation, L.L.C. v. Dep't of Health & Envtl. Quality of Mont.*, 213 F.3d 1108, 1117 n. 11 (9th Cir.2000) (internal quotation marks omitted). Here, regardless of whether federal or state law creates the cause of action underlying Santa Clara's contract claim-a question we will not reach out to resolve because the complaint is ambiguous, neither party has briefed the issue and the precedent is famously obscure, *see, e.g., Empire Healthchoice Assur., Inc. v.*

(Cont'd)

look to general principles for interpreting contracts." *Kennewick Irrigation Dist. v. United States*, 880 F.2d 1018, 1032 (9th Cir.1989). Among these principles, we interpret every part of a written contract with reference to the whole and give terms their ordinary meaning unless a contrary intent appears. *See Klamath*, 204 F.3d at 1210. When possible, we ascertain the intent of the parties from the contract itself. *See id.*

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(Cont'd)

*McVeigh*, 547 U.S. 677, 126 S.Ct. 2121, 165 L.Ed.2d 131 (2006); *Boyle v. United Tech. Corp.*, 487 U.S. 500, 506-07 & n. 3, 108 S.Ct. 2510, 101 L.Ed.2d 442 (1988); *Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union*, 457 U.S. 15, 20-23, 102 S.Ct. 2202, 72 L.Ed.2d 639 (1982); *Miree v. DeKalb County*, 433 U.S. 25, 29-31 & n. 3, 97 S.Ct. 2490, 53 L.Ed.2d 557 (1977)-it "necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities," and so was properly heard by the district court in the exercise of its 28 U.S.C. § 1331 federal question jurisdiction. *See Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005). Santa Clara seeks enforcement of an obligation created by a nationwide federal contract whose terms are mandated by federal statute and which must be interpreted according to federal law. Its claim plainly "implicate[s] the government's . . . interests" in the uniform administration of the Section 340B program and the parties' compliance with federal law. *See Smith*, 418 F.3d at 1034; *Almond v. Capital Prop., Inc.*, 212 F.3d 20, 22-24 (1st Cir.2000); *Price v. Pierce*, 823 F.2d 1114, 1119-21 (7th Cir.1987); *Eatmon v. Bristol Steel & Iron Works, Inc.*, 769 F.2d 1503, 1516-17 (11th Cir.1985); *see also Flick v. Liberty Mut. Fire Ins. Co.*, 205 F.3d 386, 390 (9th Cir.2000).

Under the federal common law of contracts, "[b]efore a third party can recover under a contract, it must show that the contract was made for its direct benefit-that it is an *intended beneficiary* of the contract." *Id.* (emphasis added). "A promisor owes a duty of performance to any intended beneficiary of the promise, and 'the intended beneficiary may enforce the duty'" by suing as a third party beneficiary of the contract, whereas an "incidental beneficiary acquires 'no right against the promisor.'" *Id.* at 1211 n. 2 (quoting Restatement (Second) of Contracts §§ 304, 315 (1979)). To qualify as an intended beneficiary, the third party "must show that the contract reflects the express or implied intention of the parties to the contract to benefit the third party." *Id.* at 1211 (citing *Montana v. United States*, 124 F.3d 1269, 1273 (Fed.Cir.1997)). Although intended beneficiaries "need not be specifically or individually identified in the contract," they still must "fall within a class clearly intended by the parties to benefit from the contract." *Id.*

Demonstrating third-party beneficiary status in the context of a government contract is a comparatively difficult task. *See Smith*, 418 F.3d at 1035; *Kremen v. Cohen*, 337 F.3d 1024, 1029 (9th Cir.2003) (explaining that a "more stringent test applies"). We have explained that "[p]arties that benefit from a government contract are generally assumed to be incidental beneficiaries," rather than intended ones, and so "may not enforce the contract *absent a clear intent to the contrary.*" *See Orff v. United States*, 358 F.3d 1137, 1145 (9th Cir.2004), *aff'd on other grounds*, 545 U.S. 596, 125 S.Ct. 2606, 162 L.Ed.2d 544

(2005) (quoting *Klamath*, 204 F.3d at 1211). This "clear intent" hurdle is not satisfied by a contract's recitation of interested constituencies, *Klamath*, 204 F.3d at 1212, "[v]ague, hortatory pronouncements," *id.*, "statement[s] of purpose," *Smith*, 418 F.3d at 1037, "explicit reference to a third party," *Orff*, 358 F.3d at 1145, or even a showing that the contract "operates to the [third parties'] benefit and was entered into with [them] 'in mind,'" *id.* at 1147. Rather, we examine the "precise language of the contract for a 'clear intent' to rebut the presumption that the [third parties] are merely incidental beneficiaries." *Id.* at 1147 n. 5.

Having done this analysis, we are persuaded that covered entities are intended beneficiaries of the PPA and, accordingly, that Santa Clara has stated a breach of contract claim on a third party beneficiary theory. At the outset, we reject the suggestion that the availability of a third party contract claim is conditioned on the contract's inclusion of a provision expressly granting the third party the *right to sue*. Any intended beneficiary has the right to enforce the obligor's duty of performance; the right to sue inheres in one's status as an intended beneficiary. *See Klamath*, 204 F.3d at 1211 n. 2; *see also Far W. Fed. Bank, S.B. v. Office of Thrift Supervision-Director*, 119 F.3d 1358, 1363 (9th Cir.1997) ("[A] third party who is an intended beneficiary of a contract may sue to enforce the contract or to obtain an appropriate remedy for breach."); Restatement (Second) of Contracts § 304 (1981). To require additionally of intended beneficiaries that the contract by its terms provide for third party enforcement would read the

distinction between incidental and intended beneficiaries out of the federal common law of contracts. *See United States v. City of Los Angeles*, 288 F.3d 391, 403-04 (9th Cir.2002) ("[W]e allowed intended third-party beneficiaries to sue . . . and did not allow incidental third-party beneficiaries to sue."); Restatement (Second) of Contracts § 302 (1981). In disavowing any absolute requirement that the contract expressly provide for third party enforcement, we reaffirm *Klamath*' s "clear intent" principle with respect to intended beneficiary status. We simply clarify that *if* the plaintiff is an *intended* beneficiary—with *Klamath* and progeny setting forth the requisite showing—then the third party contract claim may go forward.[6] Only when the plaintiff would qualify solely as an *incidental* beneficiary of the government contract is it necessary to have an express, specific statement of the promisor's contractual

6. The Manufacturers suggest that *US Ecology, Inc. v. United States*, 245 F.3d 1352 (Fed.Cir.2001), is to the contrary. Not so. The Federal Circuit declined to allow third party beneficiary enforcement of the contract because there was no "evidence of an intent by the federal government to benefit" the plaintiffs. *Id.* at 1357; *see also id.* at 1356 ("It is undisputed that the evidence contains no statement by the federal government that it intended for the alleged contract to benefit any third party."). *US Ecology* reaffirmed the principle stated in the text. "In order to create rights in a third party, 'the contract must reflect[ ] the express or implied intention of the parties to benefit the third party.'" *Id.* at 1356 (quoting Montana, 124 F.3d at 1273) (alteration in original). "One way"—but by no means the exclusive one—of ascertaining whether the parties had such an intent is to ask whether the contract expressly "confer[s] a right" to performance on third parties. *See id.* (emphasis added).

liability to that third party (such as by an express right-to-sue clause). *See Smith*, 418 F.3d at 1038; *Montana*, 124 F.3d at 1273 & n. 6; Restatement (Second) of Contracts § 313(2) & cmt. a (1981).

We hold that the parties to the PPA clearly intended to grant covered entities enforceable rights as intended beneficiaries of that agreement. *See Kremen*, 337 F.3d at 1029. In determining this central question of the parties' intent, we look at the contract's "text and purpose," *Smith*, 418 F.3d at 1034, "[e]xamin[ing] . . . the contract as a whole," *Klamath*, 204 F.3d at 1212. We also weigh the "circumstances of the transaction," *Far West*, 119 F.3d at 1364, which, when a contract is mandated by a federal statute, includes the "governing statute and its purpose," *Sec'y of State for Def. v. Trimble Navigation Ltd.*, 484 F.3d 700, 706 (4th Cir.2007) (internal quotation marks omitted); *see also Rendleman v. Bowen*, 860 F.2d 1537, 1541-42 (9th Cir.1988).

In acceding to the PPA, the Manufacturers undertook a specific responsibility to the covered entities: "Pursuant to [§ 256b], the Manufacturer *agrees* . . . . to charge *covered entities* a price for each unit of the drug that does not exceed" the ceiling price of that drug. *See* PPA § II(a) (emphasis added). *Smith*, *Kremen*, *Orff* and *Klamath*-all of which rejected plaintiffs' claims to be intended beneficiaries-are distinguishable on this ground alone.[7] There is a stark contrast between

7. *Cf. Smith*, 418 F.3d at 1036-37 (agreement simply "specifie[d] that the government's obligation . . . is subject to . . . federal law," confirmed water district's "agree[ment] to abide (Cont'd)

"recitation of constituencies," "explanatory recitals" of purpose and references to individuals that the contracting parties had "in mind"-all insufficient to "prove [the plaintiffs'] intended beneficiary status"—and the terms at issue here. *See Smith*, 418 F.3d at 1037; *Orff*, 358 F.3d at 1147; *Klamath*, 204 F.3d at 1212. Section II(a) of the PPA sets forth an unambiguous, concrete limitation on how much the Manufacturers may charge the covered entities.[8] Other provisions of the PPA explain how to calculate the ceiling price, *see* PPA §§ I(a), (b), (*l*), identify who is eligible to receive the discounted price, *see* PPA §§ I(e), III(a), and require the parties to maintain records relevant to those matters, *see* §§ PPA II(c)-(f), III(b)-(c). Upon a fair reading of

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by the terms of . . . subcontracts" and otherwise amounted to "hortatory statement[s] of purpose"); *Kremen*, 337 F.3d at 1029 (agreement only articulated defendant's responsibility to effectively, efficiently and timely manage Internet domain name registration system); *Orff*, 358 F.3d at 1145-46 (agreement "ma[de] reference" to the plaintiffs only in context of setting forth "conditions precedent" that they had to satisfy); *Klamath*, 204 F.3d at 1211-12 (agreement "grant[ed] discretion to the United States . . . to enforce the Contract by taking control of the Dam" and "preserve[d] the United States' ultimate control over the Dam").

8. Although the PPA does not state in so many words that it was entered into "for the benefit" of the covered entities, *see Far West*, 119 F.3d at 1364 n. 2, we have never conditioned our analysis of intended beneficiary status on formalistic recitals. *Cf. United States v. FMC Corp.*, 531 F.3d 813, 822 (9th Cir.2008) ("[A] contract can use whatever terms the parties wish to express their agreement.").

the PPA, we are unable to discern any substantial purpose of the PPA *other* than to grant eligible covered entities a discount on covered drugs. We are therefore persuaded that the PPA, on its face, was clearly intended to benefit the covered entities directly.

Consideration of § 256b, the "governing statute" specifying the PPA's terms, and its purposes reinforces this interpretation. *See Trimble Navigation*, 484 F.3d at 706. (The PPA itself provides that "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." *See* PPA § VII(g).) Section II(a) of the PPA closely tracks Section 602 of the Veterans Health Care Act of 1992, which was enacted to "require a manufacturer to extend the same price reduction to a covered entity for a drug or biological as is provided under the Medicaid outpatient drug rebate program." *Joint Explanatory Statement on H.R. 5193*, 138 Cong. Rec. S17890, 1992 U.S.C.C.A.N. 4186, 4211. Its purpose was "to *enable . . . certain Federally-funded clinics [i.e., covered entities] to obtain lower prices* on the drugs that they provide to their patients" by prohibiting "Medicaid matching funds [from being] available for State spending on[a manufacturer's covered drugs] unless the manufacturer enters into, and *complies with*, an agreement . . . under which these protected purchasers [e.g., covered entities] would pay the same amount for a covered outpatient drug that Medicaid pays." H.R.Rep. No. 102-384(II), at 7-8 (1992) (emphasis added). "In giving these 'covered entities' access to price reductions the Committee intends to *enable these entities* to stretch scarce Federal resources as far as

possible, reaching more eligible patients and providing more comprehensive services." *Id.* at 12 (emphasis added). Thus, although we agree with the Manufacturers that § 256b's general purpose is to "conserve federal resources so as to reach as many eligible patients as possible," the legislative history makes plain that Congress intended to accomplish this objective by enabling covered entities (and other "protected" purchasers, a revealing choice of words) to obtain discounted prices on covered drugs through the PPAs.[9]

Relying on *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir.1985), the Manufacturers contend that the PPA's provision of an "elective" or "informal" dispute resolution process means the parties intended to preclude third party enforcement of the contract by the covered entities. Sections IV(a), (b) and (d) of the PPA allow manufacturers to refer certain disputes they have with covered entities to the Secretary to conduct an investigation. If the Secretary then finds that the covered entity is in violation, he may impose monetary liability or remove the entity from the list of eligible entities.[10] Conversely, if the Secretary believes a

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9. Protected purchasers also include the Department of Veterans Affairs, the Department of Defense, the Public Health Service and the Indian Health Service. *See* Veterans Health Care Act of 1992 § 603(a), Pub.L. No. 102-585, 106 Stat. 4943, 4972 (codified at 38 U.S.C. § 8126(b)); H.R.Rep. No. 102-384(II), at 7-8.

10. The informal dispute resolution remedies against the covered entities run through the Secretary, who has the power (Cont'd)

manufacturer has overcharged covered entities, he may initiate an "informal dispute resolution process," which could result in the covered entities being reimbursed and the manufacturer's PPA being terminated. *See* PPA § IV(c). The Manufacturers also cite DHHS's regulations, which, apart from the PPA, establish a "voluntary process for the resolution of certain disputes between manufacturers and covered entities concerning compliance with the provisions" of § 256b. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed.Reg. 65,406-01, 65,411-13 (Dec. 12, 1996). This process is also voluntary: "Covered entities or manufacturers are not required to enter this informal process for resolution of disputes. . . ." *Id.* at 65,411.

*D'Amato* does not support the Manufacturers' argument. There, the plaintiffs attempted to bring suit as third party beneficiaries of affirmative action provisions whose inclusion in procurement contracts was required by Section 503 of the Rehabilitation Act of 1973. As a threshold matter, the contracts themselves suggested that the plaintiffs were not intended beneficiaries; they were "not directed at the

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to "establish a mechanism to ensure that covered entities comply" with the Section 340B program's requirements and sanction them for noncompliance. *See* § 256b(a)(5)(A)(ii), (D). We construe these PPA provisions as simply restating the covered entities' statutory obligations, because as a matter of federal common law, even a third party beneficiary "cannot be bound to a contract it did not sign." *See Comer v. Micor, Inc.*, 436 F.3d 1098, 1102 (9th Cir.2006).

handicapped in any way but instead focus[ed] exclusively on the government—contractor relationship." *D'Amato*, 760 F.2d at 1479. The court found *further* support for its conclusion that the disabled were not intended beneficiaries in Section 503 and its implementing regulations, which established an administrative remedy for any "handicapped individual [who] believe[d] any contractor has failed .... to comply" with the affirmative action provisions and emphasized the resolution of disputes "by informal means, including conciliation[ ] and persuasion." *See id.* at 1477 n. 1, 1481-82 (citing 29 U.S.C. § 793(b) and 41 C.F.R. § 60-741.28(a) (1984)).

We perceive four material differences between the contract and statute in *D'Amato* and those here. First, as discussed above, the PPA sets forth the contracting parties' clear intent to directly benefit the covered entities. *Cf. id.* at 1479-80. Second, § 256b says nothing about the covered entities' remedies, whether judicial or administrative. *Cf. id.* at 1481 ("The statutory grant of *one* remedy . . . without mention of any other . . . implies that Congress intended to bar *other* remedies.") (emphasis added). Third, allowing covered entities to bring suit as third party beneficiaries would not conflict with the PPA's informal dispute resolution process, given that the entities themselves are unable to initiate that process.[11] Last, the voluntary administrative dispute

11. *Cf. FMC Corp.*, 531 F.3d at 823 (declining to recognize intended beneficiary status because that would "grant a broader range of dispute-resolving rights to [third parties] than to the [contracting] parties," who were required to exhaust the contract's "prescribed dispute resolution mechanisms" before (Cont'd)

resolution procedure created by DHHS's regulations expressly leaves open resort to "other remedies which may be available under applicable principles of law." *See* 61 Fed.Reg. at 65,412; *see also id.* at 65,411 ("[Covered] entities are only encouraged to participate in the process before seeking other remedies."). In sum, neither the PPA nor § 256b establishes an exclusive "elaborate administrative procedure," *D'Amato*, 760 F.2d at 1482, that—were such a procedure to exist-would signal the parties' intent to deny covered entities the right to enforce the PPA through litigation as intended beneficiaries.

The Manufacturers' remaining arguments against the covered entities' intended beneficiary status are no more convincing. First, they contend it is "illogical" that the United States and the Manufacturers would have intended to expose themselves to suit by the large number of covered entities, about 13,000 reported as of this writing.[12] The breadth and indefiniteness of a class of beneficiaries is entitled to some weight in negating the inference of intended beneficiary status. *See Price*

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bringing suit). By contrast, the PPA provides that its informal dispute resolution process will not "preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law." *See* PPA § IV(e).

12. *See* Department of Health and Human Services, Office of Pharmacy Affairs, *Growth of 340B Covered Entity Sites From 01/1998 to Present*, http:// opanet. hrsa. gov/ opa/ Report/ Statistical Report. aspx.

*v. Pierce*, 823 F.2d 1114, 1121 (7th Cir.1987) (commenting that parties would not likely have intended that "almost every lower-income person in the United States" could enforce the contract). But numbers alone are not determinative. For example, in *Hook v. State of Ariz., Dep't of Corr.*, 972 F.2d 1012, 1014-15 (9th Cir.1992), we recognized all inmates of the Arizona prison system as intended beneficiaries of a consent decree regulating mail policies. Similarly in this case, covered entities constitute a narrow, well-defined class, not at all akin to members of the public at large. *See* § 256b(a)(4) (defining "covered entity"); PPA § III(a) (making available list of eligible covered entities), § IV(b) (procedure for challenging eligibility of covered entities).

We are also unmoved by the Manufacturers' protest that they "surely would not have agreed to subject themselves to a large number of lawsuits that could undermine the confidentiality" of pricing data through discovery, given the PPA's inclusion of a confidentiality provision.[13] The confidentiality provision itself, however,

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13. This argument is problematic for another, more pragmatic reason, which is that the PPA was not a conventionally negotiated contract. Presumably, the Manufacturers would have preferred not to give covered entities any discount at all, but they faced an overwhelmingly powerful incentive to accept the PPA. Eligibility for a number of substantial federal healthcare programs is conditioned on having an effective § 256b agreement with the Secretary. *See* § 1396r-8(a)(1), (a)(5)(A); *see generally Joint Explanatory Statement on H.R. 5193*, 138 Cong. Rec. S17890, 1992

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contemplates that such information could well be subject to disclosure for purposes of enforcing the PPA's discount pricing requirements beyond any actions the Secretary might initiate. Section V(a) specifies that information disclosed to the Secretary by the Manufacturers, "*except as otherwise required by law,* will not be disclosed *by the Secretary or his designee* in a form which reveals the Manufacturer, except as necessary to carry out the provisions of [§ 256b] and to permit review by the [OIG]." (Emphasis added.) As the italicized phrases highlight, the confidentiality provision anticipates that disclosures could be required other than to or by the Secretary. A district court's discovery order compelling the production of documents would be a disclosure "required by law"; and it would be the manufacturer, not the Secretary, disclosing the information. To the extent a drug company would rightly be concerned about sensitive pricing information, district courts routinely enter protective orders to prevent the undue disclosure of commercially sensitive information. *See* Fed.R.Civ.P. 26(c); *Phillips ex rel. Estates of Byrd v. Gen. Motors Corp.*, 307 F.3d 1206, 1210-12 (9th Cir.2002). Thus we are unwilling to read the PPA's confidentiality proviso as negating third party covered entities' right to enforce the discount pricing requirements themselves.

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U.S.C.C.A.N. 4186, 4211 (explaining that § 256b makes the "use of federal matching funds for payment for a covered outpatient drug [by State Medicaid programs] . . . contingent on . . . a manufacturer's entering into [ ] an agreement . . . under which the manufacturer agrees to provide rebates or discounts to" covered entities).

## II.

Although we conclude that covered entities are intended beneficiaries of the PPA, and so would ordinarily be entitled to bring suit to enforce it, the Manufacturers urge that this is not the usual intended beneficiary case and that permitting third party enforcement of the PPA would conflict with Congress' intent in creating the Section 340B program.[14] In this vein, they point to Santa Clara's concession before the district court that there is no private federal cause of action under § 256b.[15] *See generally Alexander v. Sandoval*, 532 U.S. 275, 121 S.Ct. 1511, 149 L.Ed.2d 517 (2001). Because Congress did not provide a *statutory* remedy, the Manufacturers argue, it necessarily did not intend to allow covered entities to make an "end-run" around the statutory scheme by pursuing *contractual* remedies under the federal common law.

The starting point of this argument is the truism that federal common law, of which the federal common

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14. Although this argument was raised for the first time in the Manufacturers' reply to Santa Clara's opposition to its motion to dismiss and the district court did not address it, we will pass on the merits here. The issue is one of law and has been fully briefed by both parties. *See Pocatello Educ. Ass'n v. Heideman*, 504 F.3d 1053, 1060 n. 5 (9th Cir.2007); *Bibeau v. Pac. Northwest Research Foundation Inc.*, 188 F.3d 1105, 1111 n. 5 (9th Cir.1999)..

15. Santa Clara has not pursued this matter on appeal, so we assume without deciding that § 256b does not create a private cause of action.

law of contracts forms a part, "is 'subject to the paramount authority of Congress.'" *City of Milwaukee v. Illinois & Michigan*, 451 U.S. 304, 313, 101 S.Ct. 1784, 68 L.Ed.2d 114 (1981) (quoting *New Jersey v. New York*, 283 U.S. 336, 348, 51 S.Ct. 478, 75 L.Ed. 1104 (1931)). We presume that Congress legislates with the expectation that the principles of the federal common law "will apply except 'when a statutory purpose to the contrary is evident.'" *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 108, 111 S.Ct. 2166, 115 L.Ed.2d 96 (1991) (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783, 72 S.Ct. 1011, 96 L.Ed. 1294 (1952)). However, when Congress "speak[s] directly" to a question addressed by the federal common law, it may displace it even without "affirmatively proscrib[ing]" its use. *United States v. Texas*, 507 U.S. 529, 534, 113 S.Ct. 1631, 123 L.Ed.2d 245 (1993); *see also Gardiner v. Sea-Land Service, Inc.*, 786 F.2d 943, 947 (9th Cir.1986). "In evaluating the displacement issue, courts must assess the scope of the legislation and whether the legislative scheme addresses the problem formerly governed by federal common law." *Gardiner*, 786 F.2d at 947.[16] The

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16. This is a different and less demanding inquiry than that used to evaluate whether a federal statute preempts a state-law cause of action, *see City of Milwaukee*, 451 U.S. at 316-17, 101 S.Ct. 1784; *cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), or whether a federal statute's comprehensive remedial scheme impliedly displaces a more general federal private cause of action such as 42 U.S.C. § 1983, *see Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 20-21, 101 S.Ct. 2615, 69 L.Ed.2d

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Manufacturers, relying almost exclusively on *Grochowski v. Phoenix Constr.*, 318 F.3d 80 (2d Cir.2003), contend that § 256b does just that and, therefore, to allow covered entities to enforce the PPA as a matter of contract would be inconsistent with Congress' choice of remedies.

In *Grochowski*, the Second Circuit did not permit the plaintiffs to bring suit as third party beneficiaries of a contract between the contractor defendants and New York City's public housing authority. *See* 318 F.3d at 83. Under the Davis-Bacon Act, 40 U.S.C. § 3141, all construction contracts for federally funded projects must include the following provision: "[t]he Contractor shall pay to all laborers . . . not less than the wages prevailing in the locality of the Project, as predetermined by the Secretary of Labor of the United States." *Id.* (first alteration in original). Exercising his authority under 40 U.S.C. § 3145 to "prescribe reasonable regulations for contractors" subject to the Davis-Bacon Act, the Secretary of Labor established an administrative remedial scheme. *See id.* at 85; *Chan v.*

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435 (1981); *Flores v. Arizona*, 516 F.3d 1140, 1174-75 (9th Cir.2008). *See generally Resolution Trust Corp. v. Frates*, 52 F.3d 295, 296-97 (10th Cir.1995) (explaining difference between preemption of state law and supersession of the federal common law). We conclude that § 256b does not abrogate the cause of action ordinarily provided by the federal common law of contracts; thus it does not preempt a state-law contract cause of action, if that indeed is how Santa Clara's claim should be characterized. *See supra* note 5.

*City of New York*, 1 F.3d 96, 102 (2d Cir.1993) (citing 29 C.F.R. §§ 1.8, 5.6(a)(3), 5.11). Given these administrative remedies, and the absence of an explicit private cause of action, *Grochowski* concluded that the "plaintiffs['] efforts to bring their claims as state common-law [contract] claims [were] clearly an impermissible 'end run'" around congressional intent as to the availability of remedies under the Davis-Bacon Act. 318 F.3d at 86.

Assuming *Grochowski* was correctly decided, the case is clearly inapposite on its own terms.[17] Its analytical underpinning was the "'elemental canon' of statutory construction that where a *statute expressly provides a remedy*, 'courts must be especially reluctant to provide *additional* remedies.'" *Id.* at 85 (quoting *Karahalios v. Nat'l Fed'n of Employees, Local 1263*, 489 U.S. 527, 533, 109 S.Ct. 1282, 103 L.Ed.2d 539 (1989)) (emphasis added). Here, § 256b does not "expressly provide" any remedies to covered entities.[18] And unlike the Davis-

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17. Because the *Grochowski* plaintiffs' contract claims were based on state law, not federal law, it is puzzling that the majority did not frame its analysis in terms of whether Congress intended to preempt those claims. *See, e.g., Grochowski*, 318 F.3d at 90-91 (Lynch, J. dissenting); *Cox v. NAP Constr. Co., Inc.*, 10 N.Y.3d 592, 603-07, 861 N.Y.S.2d 238, 891 N.E.2d 271 (N.Y.2008).

18. Section 256b does provide a number of remedies *against* covered entities. *See, e.g.*, § 256b(a)(5)(C) ("A covered entity shall permit the Secretary and [manufacturers] . . . to audit . . . records of the entity that directly pertain to the entity's compliance" with the program.); (a)(5)(D) ("If the Secretary finds . . . that a covered entity is in violation . . . the covered entity shall be liable. . . .").

Bacon Act, § 256b is silent about the agency's power to promulgate regulations against *manufacturers* with the force of law. *Cf.* § 256b(a)(5)(A)(ii) ("The Secretary shall establish a mechanism to ensure that *covered entities* comply . . . .") (emphasis added). Although the Secretary may terminate the PPA with a manufacturer for a violation of its provisions, this remedy is a matter of contract, not statute. *See* PPA § VI(c). Reflecting this paucity of statutory authority, DHHS's regulations establish only an informal, nonexclusive dispute resolution process, in which neither covered entities nor manufacturers are required to participate. *See* 61 Fed.Reg. at 65,411. Nothing in the statute suggests that Congress intended that DHHS create a substitute, administrative remedial scheme for covered entities to invoke against manufacturers. Thus, there is nothing "additional" about the federal common law contract remedy that the covered entities could invoke as intended beneficiaries of the PPA. *Cf. Golt v. United States*, 186 F.3d 1158, 1164 (9th Cir.1999) (holding that Civil Service Reform Act, which expressly created exclusive administrative remedy, abrogated remedies under federal common law).

Permitting covered entities to sue as intended beneficiaries of the PPA is therefore wholly compatible with the Section 340B program's objectives. *Cf. Trimble Navigation*, 484 F.3d at 707 ("[R]ecognition of third-party beneficiary status in a contract made under a statutory scheme must accord with that scheme. . . ."); Restatement (Second) of Contracts § 313(1) (1981) (limiting application of third party beneficiary doctrine

when it "would contravene the policy of the law authorizing the contract or prescribing remedies for its breach"). As we have explained, the Section 340B program was created to give covered entities discounts so they could "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R.Rep. No. 102-384(II), at 12 (1992). Federal common law contract remedies are one way of ensuring that drug companies comply with their obligations under the program and provide those discounts. *See Price*, 823 F.2d at 1121 (observing that it "seemed more sensible" to permit third parties to sue as intended beneficiaries than to "place the entire burden of enforcement" on the government).

## III.

Finally, we decline at this time to invoke the doctrine of primary jurisdiction, which would require that Santa Clara's contract claim be stayed or dismissed without prejudice pending its referral to the Secretary for agency resolution. The doctrine of primary jurisdiction "is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir.2002). "[P]rimary jurisdiction is properly invoked when a claim is cognizable in federal court but requires resolution of an issue of first impression, or of a particularly complicated issue that

Congress has committed to a regulatory agency." *Id.* (quoting *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1172 (9th Cir.2002)). The doctrine does not require that all claims touching on an agency's expertise first be decided by the agency, however. *See id.* "The particular agency deferred to must be one that Congress has vested with the authority to regulate an industry or activity such that it would be inconsistent with the statutory scheme to deny the agency's power to resolve the issues in question." *United States v. Culliton*, 328 F.3d 1074, 1082 (9th Cir.2003) (internal quotation marks omitted). To determine whether primary jurisdiction should be applied, we have "employed such factors as (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek*, 307 F.3d at 781.

In determining whether to invoke primary jurisdiction, we also consider the procedural posture of the case. At the motion to dismiss stage, we apply a standard derived from Rule 12(b)(6) jurisprudence: whether the complaint plausibly asserts a claim that would *not* implicate the doctrine. *See Ashcroft v. Iqbal*, __ U.S. __, 129 S.Ct. 1937, 1949, 173 L.Ed.2d 868 (2009) (requiring that a complaint be facially plausible to survive a motion to dismiss); *Davel Commc'ns, Inc. v. Qwest Corp.*, 460 F.3d 1075, 1088 (9th Cir.2006) (noting that the Rule 12(b)(6) standard governs a primary

jurisdiction claim). Having been advised of the Secretary's views, we conclude that Santa Clara's complaint does not require referral under this standard.[19] At this stage, the nature of the breaches Santa Clara will seek to prove is unclear, but the Secretary has indicated that at least some possible disputes could be resolved by a court without DHHS's expertise. Thus, we decline to invoke primary jurisdiction at this time, but leave open the possibility that the district court may decide after further factual development that referral to the Secretary is appropriate.

## CONCLUSION

As intended direct beneficiaries of the PPA, covered entities may enforce the Manufacturers' ceiling price obligations under the federal common law of contracts. Although the statute mandating the PPA does not create a federal private cause of action, allowing Santa Clara's contract claim to go forward is consistent with Congress' intent in enacting the legislative scheme. Because that claim could plausibly be adjudicated without DHHS's expertise, invoking primary jurisdiction is not appropriate at this time.

**REVERSED and REMANDED.**

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19. At our invitation, the United States submitted a brief to articulate the Secretary's views on whether we should invoke primary jurisdiction to allow DHHS to resolve Santa Clara's claims. *See* Brief for the United States of America as Amicus Curiae in Support of the Judgment Below, *County of Santa Clara v. AstraZeneca Pharmaceuticals LP*, No. 09-15216, 2009 WL 4089524 (9th Cir. Oct. 27, 2009); *cf. supra* note *.

## APPENDIX B — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT FILED AUGUST 27, 2008

**UNITED STATES COURT OF APPEALS**
**NINTH CIRCUIT**

**No. 06-16471.**

COUNTY OF SANTA CLARA,

Plaintiff-Appellant,

v.

ASTRA USA, INC.; AstraZeneca Pharmaceuticals LP; Aventis Pharmaceuticals, Inc.; Bayer Corporation; Bristol-Myers Squibb Company; Pfizer, Inc.; Schering-Plough Corporation TAP Pharmaceutical Products, Inc.; Zenecca Inc.; ZLB Behring LLC; SmithKline Beecham Corporation; SmithKline Beecham Corporation, dba GlaxoSmithKline; Wyeth, Inc.; Wyeth Pharmaceuticals, Inc.,

Defendants-Appellees.

Argued and Submitted March 11, 2008.
Filed Aug. 27, 2008.

Appeal from the United States District Court for the Northern District of California; William H. Alsup, District Judge, Presiding. D.C. No. CV-05-03740-WHA.

*Appendix B*

Before: STEPHEN REINHARDT, MELVIN BRUNETTI and RAYMOND C. FISHER, Circuit Judges.

FISHER, Circuit Judge:

Certain federally funded medical clinics-so-called "Section 340B covered entities"—are able to purchase prescription drugs at a discount from drug manufacturers under a standardized agreement between the federal government and the drug companies. During 2003, for example, these covered entities spent $3.4 billion on outpatient prescription drugs. They claim in this lawsuit that they have been overcharged for those drugs in violation of pharmaceutical pricing agreements between the Secretary of Health and Human Services ("Secretary") and the drug manufacturer defendants-appellees ("Manufacturers"). Applying the federal common law of contracts, we hold that the covered entities are intended direct beneficiaries of these agreements and thus have the right to enforce the agreements' discount provisions against the Manufacturers and sue them for reimbursement of excess payments. We have jurisdiction under 28 U.S.C. § 1291, and reverse the district court's dismissal of the complaint under Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim.

*Appendix B*

## BACKGROUND[1]

In part to "enable . . . certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients," *see* H.R.Rep. No. 102-384(II), at 7 (1992), Congress enacted Section 602 of the Veterans Health Care Act of 1992, Pub.L. No. 102-585, 106 Stat. 4943, 4967. That provision, entitled "Limitations on Prices of Drugs Purchased by Covered Entities," requires the Secretary of Health and Human Services to:

> enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug under [§ 1396r-8(k)(1) ] in the preceding calendar quarter, reduced by [a] rebate percentage described in [§ 256b(a)(2)].

42 U.S.C. § 256b(a)(1).[2] This drug discounting program is commonly known as the "Section 340B program,"

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1. Because this is an appeal from an order granting a motion to dismiss, we accept all facts alleged as true and construe them in the light most favorable to the plaintiff. *See Karam v. City of Burbank*, 352 F.3d 1188, 1192 (9th Cir.2003).

2. Hereinafter, all citations are to Title 42 of the United States Code unless otherwise noted.

tracing back to its original location within the Public Health Service Act.[3] The program is managed by the Health Resources and Services Administration ("HRSA"), a subdivision of the Department of Health and Human Services ("DHHS"). *See* Statement of Organizations, Functions, and Delegations of Authority, 58 Fed.Reg. 19,137-02 (Apr. 12, 1993). In accordance with statute, the Secretary entered into a standard Pharmaceutical Pricing Agreement ("PPA") with each of the Manufacturers.

One of the Manufacturers' principal obligations under the PPA is "to charge covered entities a price . . . that does not exceed . . . the [average manufacturer price] for the covered outpatient drug reported . . . to the Secretary in accordance with the Manufacturer's responsibilities under [§ 1396r-8(b)(3)], reduced by the rebate percentage." *See* PPA § II(a).[4] The PPA defines "average manufacturer price," "covered entity," "manufacturer" and "rebate percentage" to "have the meanings specified in [§§ 256b and 1396r-8], as interpreted and applied herein." *See* PPA §§ I(a)-(*o*). Also known as the "ceiling price,"

3. Section 602 of the Veterans Health Care Act of 1992 added a new Section 340B to Part D of Title III of the Public Health Service Act. *See* 106 Stat. at 4967. The Public Health Service Act is itself codified at Chapter 6A of Title 42 of the United States Code. *See* National Institutes of Health Revitalization Act of 1993 § 2008(i)(1)-(2), Pub.L. No. 103-43, 107 Stat. 122, 212-13.

4. The PPA establishes different discounts for other classes of drugs that are not relevant here. *See* PPA §§ II(b)-(c).

the maximum price that covered entities may be charged under the PPA is calculated using proprietary sales and pricing information the Manufacturers disclose only to the Secretary.

The genesis of the present appeal is a putative class action filed in California state court by the county of Santa Clara and a number of county-operated medical facilities ("Santa Clara"), which are covered entities within the meaning of § 256b(a)(4) and PPA § I(e). Relying chiefly on reports published by DHHS's Office of the Inspector General ("OIG"), Santa Clara alleged that the Manufacturers have systematically overcharged its medical facilities, and all similarly situated covered entities, for covered drugs. OIG's March 2003 report estimated that overcharges during the one-year period ending September 1999 totaled $6.1 million. Its June 2004 report, which was withdrawn in October 2004 because of "problems with the underlying data," concluded that covered entities overpaid $41.1 million in the month of September 2002. In October 2005, OIG confirmed that its June 2004 calculation was erroneous because the Centers for Medicare and Medicaid Services had provided it with comparison "ceiling prices from the wrong timeframe." OIG did not retreat, however, from its other, more general findings that HRSA was not adequately overseeing the Section 340B program and that "HRSA lacks the oversight mechanisms and authority to ensure that [covered] entities pay at or below the . . . ceiling price." The October 2005 report also "introduce[d] new concerns" that "systemic problems with the accuracy

and reliability" of the government's pricing data could interfere with HRSA's ability to monitor the Section 340B program. Finally, a 2006 OIG report estimated that covered entities overpaid $3.9 million in June 2005 alone.

Santa Clara initially brought claims under the California False Claims Act and California Unfair Competition Law in state court. After the Manufacturers removed the action to federal district court, Santa Clara amended its complaint for the first time. The district court granted the Manufacturers' motion to dismiss, but with leave to amend. Santa Clara's second amended complaint, now including claims for breach of the PPA, breach of the implied covenant of good faith and fair dealing, negligence and quantum meruit, fared no better than the first. The district court granted the Manufacturers' second motion to dismiss and denied as futile Santa Clara's subsequent motion for leave to file a third amended complaint. Santa Clara appeals only the district court's rejection of its PPA breach of contract claim on a third party beneficiary theory.

## STANDARD OF REVIEW

"We review de novo the district court's dismissal of a complaint for failure to state a claim under Rule 12(b)(6)." *Vasquez v. Los Angeles County*, 487 F.3d 1246, 1249 (9th Cir.2007). The interpretation of a contract is a mixed question of law and fact that we review de novo. *Klamath Water Users Protective Ass'n v. Patterson*, 204 F.3d 1206, 1210 (9th Cir.1999).

*Appendix B*

## DISCUSSION

We agree with Santa Clara that covered entities are intended direct beneficiaries of the PPA and have the right as third parties to bring claims for breach of that contract. We also conclude that allowing such suits under the PPA is consistent with Congress' intent in enacting the Section 340B program, even though the statute itself does not create a federal private cause of action. Finally, we reject the Manufacturers' argument that primary jurisdiction is appropriate.

### I.

Federal law controls the interpretation of the PPA, which is a "contract[ ] entered into pursuant to federal law and to which the government is a party," *Smith v. Cent. Ariz. Water Conservation Dist.*, 418 F.3d 1028, 1034 (9th Cir.2005), and which expressly provides that it "shall be construed in accordance with Federal common law," *see* PPA § VII(g).[5] "For guidance, we may

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5. "[F]ederal jurisdiction cannot be created by contract," of course, and we have an independent obligation to scrutinize our jurisdiction. *ARCO Envtl. Remediation, L.L.C. v. Dep't of Health & Envtl. Quality of Mont.*, 213 F.3d 1108, 1117 n. 11 (9th Cir.2000) (internal quotation marks omitted). Here, regardless of whether federal or state law creates the cause of action underlying Santa Clara's contract claim—a question we will not reach out to resolve because the complaint is ambiguous, neither party has briefed the issue and the precedent is famously obscure, *see, e.g., Empire Healthchoice Assur., Inc. v.*

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look to general principles for interpreting contracts." *Kennewick Irrigation Dist. v. United States*, 880 F.2d 1018, 1032 (9th Cir.1989). Among these principles, we interpret every part of a written contract with reference to the whole and give terms their ordinary meaning unless a contrary intent appears. *See Klamath*, 204 F.3d at 1210. When possible, we ascertain the intent of the parties from the contract itself. *See id.*

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*McVeigh*, 547 U.S. 677, 126 S.Ct. 2121, 165 L.Ed.2d 131 (2006); *Boyle v. United Tech. Corp.*, 487 U.S. 500, 506-07 & n. 3, 108 S.Ct. 2510, 101 L.Ed.2d 442 (1988); *Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union*, 457 U.S. 15, 20-23, 102 S.Ct. 2202, 72 L.Ed.2d 639 (1982); *Miree v. DeKalb County*, 433 U.S. 25, 29-31 & n. 3, 97 S.Ct. 2490, 53 L.Ed.2d 557 (1977)—it "necessarily raise[s] a stated federal issue, actually disputed and substantial, which a federal forum may entertain without disturbing any congressionally approved balance of federal and state judicial responsibilities," and so was properly heard by the district court in the exercise of its 28 U.S.C. § 1331 federal question jurisdiction. *See Grable & Sons Metal Prod., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314, 125 S.Ct. 2363, 162 L.Ed.2d 257 (2005). Santa Clara seeks enforcement of an obligation created by a nationwide federal contract whose terms are mandated by federal statute and which must be interpreted according to federal law. Its claim plainly "implicate[s] the government's . . . interests" in the uniform administration of the Section 340B program and the parties' compliance with federal law. *See Smith*, 418 F.3d at 1034; *Almond v. Capital Prop., Inc.*, 212 F.3d 20, 22-24 (1st Cir.2000); *Price v. Pierce*, 823 F.2d 1114, 1119-21 (7th Cir.1987); *Eatmon v. Bristol Steel & Iron Works, Inc.*, 769 F.2d 1503, 1516-17 (11th Cir.1985); *see also Flick v. Liberty Mut. Fire Ins. Co.*, 205 F.3d 386, 390 (9th Cir.2000).

*Appendix B*

Under the federal common law of contracts, "[b]efore a third party can recover under a contract, it must show that the contract was made for its direct benefit—that it is an *intended beneficiary* of the contract." *Id.* (emphasis added). "A promisor owes a duty of performance to any intended beneficiary of the promise, and 'the intended beneficiary may enforce the duty'" by suing as a third party beneficiary of the contract, whereas an "incidental beneficiary acquires 'no right against the promisor.'" *Id.* at 1211 n. 2 (quoting Restatement (Second) of Contracts §§ 304, 315 (1979)). To qualify as an intended beneficiary, the third party "must show that the contract reflects the express or implied intention of the parties to the contract to benefit the third party." *Id.* at 1211 (citing *Montana v. United States*, 124 F.3d 1269, 1273 (Fed.Cir.1997)). Although intended beneficiaries "need not be specifically or individually identified in the contract," they still must "fall within a class clearly intended by the parties to benefit from the contract." *Id.*

Demonstrating third-party beneficiary status in the context of a government contract is a comparatively difficult task. *See Smith*, 418 F.3d at 1035; *Kremen v. Cohen*, 337 F.3d 1024, 1029 (9th Cir.2003) (explaining that a "more stringent test applies"). We have explained that "[p]arties that benefit from a government contract are generally assumed to be incidental beneficiaries," rather than intended ones, and so "may not enforce the contract *absent a clear intent to the contrary.*" *See Orff v. United States*, 358 F.3d 1137, 1145 (9th Cir.2004), *aff'd on other grounds*, 545 U.S. 596, 125 S.Ct. 2606, 162 L.Ed.2d 544

(2005) (quoting *Klamath*, 204 F.3d at 1211). This "clear intent" hurdle is not satisfied by a contract's recitation of interested constituencies, *Klamath*, 204 F.3d at 1212, "[v]ague, hortatory pronouncements," *id.*, "statement[s] of purpose," *Smith*, 418 F.3d at 1037, "explicit reference to a third party," *Orff*, 358 F.3d at 1145, or even a showing that the contract "operates to the [third parties'] benefit and was entered into with [them] 'in mind,'" *id.* at 1147. Rather, we examine the "precise language of the contract for a 'clear intent' to rebut the presumption that the [third parties] are merely incidental beneficiaries." *Id.* at 1147 n. 5.

Having done this analysis, we are persuaded that covered entities are intended beneficiaries of the PPA and, accordingly, that Santa Clara has stated a breach of contract claim on a third party beneficiary theory. At the outset, we reject the suggestion that the availability of a third party contract claim is conditioned on the contract's inclusion of a provision expressly granting the third party the *right to sue*. Any intended beneficiary has the right to enforce the obligor's duty of performance; the right to sue inheres in one's status as an intended beneficiary. *See Klamath*, 204 F.3d at 1211 n. 2; *see also Far W. Fed. Bank, S.B. v. Office of Thrift Supervision-Director*, 119 F.3d 1358, 1363 (9th Cir.1997) ("[A] third party who is an intended beneficiary of a contract may sue to enforce the contract or to obtain an appropriate remedy for breach."); Restatement (Second) of Contracts § 304 (1981). To require additionally of intended beneficiaries that the contract by its terms provide for third party enforcement would read the

distinction between incidental and intended beneficiaries out of the federal common law of contracts. *See United States v. City of Los Angeles*, 288 F.3d 391, 403-04 (9th Cir.2002) ("[W]e allowed intended third-party beneficiaries to sue . . . and did not allow incidental third-party beneficiaries to sue."); Restatement (Second) of Contracts § 302 (1981). In disavowing any absolute requirement that the contract expressly provide for third party enforcement, we reaffirm *Klamath*'s "clear intent" principle with respect to intended beneficiary status. We simply clarify that *if* the plaintiff is an *intended* beneficiary—with *Klamath* and progeny setting forth the requisite showing—then the third party contract claim may go forward.[6] Only when the plaintiff would qualify solely as an *incidental* beneficiary of the government contract is it necessary to have an express, specific statement of the promisor's contractual

6. The Manufacturers suggest that *US Ecology, Inc. v. United States*, 245 F.3d 1352 (Fed.Cir.2001), is to the contrary. Not so. The Federal Circuit declined to allow third party beneficiary enforcement of the contract because there was no "evidence of an intent by the federal government to benefit" the plaintiffs. *Id.* at 1357; *see also id.* at 1356 ("It is undisputed that the evidence contains no statement by the federal government that it intended for the alleged contract to benefit any third party."). *US Ecology* reaffirmed the principle stated in the text. "In order to create rights in a third party, 'the contract must reflect[ ] the express or implied intention of the parties to benefit the third party.'" *Id.* at 1356 (quoting *Montana*, 124 F.3d at 1273) (alteration in original). "*One* way"—but by no means the exclusive one-of ascertaining whether the parties had such an intent is to ask whether the contract expressly "confer[s] a right" to performance on third parties. *See id.* (emphasis added).

liability to that third party (such as by an express right-to-sue clause). *See Smith*, 418 F.3d at 1038; *Montana*, 124 F.3d at 1273 & n. 6; Restatement (Second) of Contracts § 313(2) & cmt. a (1981).

We hold that the parties to the PPA clearly intended to grant covered entities enforceable rights as intended beneficiaries of that agreement. *See Kremen*, 337 F.3d at 1029. In determining this central question of the parties' intent, we look at the contract's "text and purpose," *Smith*, 418 F.3d at 1034, "[e]xamin[ing] . . . the contract as a whole," *Klamath*, 204 F.3d at 1212. We also weigh the "circumstances of the transaction," *Far West*, 119 F.3d at 1364, which, when a contract is mandated by a federal statute, includes the "governing statute and its purpose," *Sec'y of State for Def. v. Trimble Navigation Ltd.*, 484 F.3d 700, 706 (4th Cir.2007) (internal quotation marks omitted); *see also Rendleman v. Bowen*, 860 F.2d 1537, 1541-42 (9th Cir.1988).

In acceding to the PPA, the Manufacturers undertook a specific responsibility to the covered entities: "Pursuant to [§ 256b], the Manufacturer *agrees* . . . . to charge *covered entities* a price for each unit of the drug that does not exceed" the ceiling price of that drug. *See* PPA § 11(a) (emphasis added). *Smith*, *Kremen*, *Orff* and *Klamath*—all of which rejected plaintiffs' claims to be intended beneficiaries-are distinguishable on this ground alone.[7] There is a stark contrast between

7. *Cf. Smith*, 418 F.3d at 1036-37 (agreement simply "specifie[d] that the government's obligation . . . is subject to . . . federal law," confirmed water district's "agree[ment] to abide

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"recitation of constituencies," "explanatory recitals" of purpose and references to individuals that the contracting parties had "in mind"—all insufficient to "prove [the plaintiffs'] intended beneficiary status"-and the terms at issue here. *See Smith*, 418 F.3d at 1037; *Orff*, 358 F.3d at 1147; *Klamath*, 204 F.3d at 1212. Section II(a) of the PPA sets forth an unambiguous, concrete limitation on how much the Manufacturers may charge the covered entities.[8] Other provisions of the PPA explain how to calculate the ceiling price, *see* PPA §§ I(a), (b), (*l*), identify who is eligible to receive the discounted price, *see* PPA §§ I(e), III(a), and require the parties to maintain records relevant to those matters, *see* §§ PPA II(e)-(f), III(b)-(c). Upon a fair reading of

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by the terms of . . . subcontracts" and otherwise amounted to "hortatory statement[s] of purpose"); *Kremen*, 337 F.3d at 1029 (agreement only articulated defendant's responsibility to effectively, efficiently and timely to manage Internet domain name registration system); *Orff*, 358 F.3d at 1145-46 (agreement "ma[de] reference" to the plaintiffs only in context of setting forth "conditions precedent" that they had to satisfy); *Klamath*, 204 F.3d at 1211-12 (agreement "grant[ed] discretion to the United States . . . to enforce the Contract by taking control of the Dam" and "preserve[d] the United States' ultimate control over the Dam").

8. Although the PPA does not state in so many words that it was entered into "for the benefit" of the covered entities, *see Far West*, 119 F.3d at 1364 n. 2, we have never conditioned our analysis of intended beneficiary status on formalistic recitals. *Cf. United States v. FMC Corp.*, 531 F.3d 813, 822 (9th Cir.2008) ("[A] contract can use whatever terms the parties wish to express their agreement.").

the PPA, we are unable to discern any substantial purpose of the PPA *other* than to grant eligible covered entities a discount on covered drugs. We are therefore persuaded that the PPA, on its face, was clearly intended to benefit the covered entities directly.

Consideration of § 256b, the "governing statute" specifying the PPA's terms, and its purposes reinforces this interpretation. *See Trimble Navigation*, 484 F.3d at 706. (The PPA itself provides that "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." *See* PPA § VII(g).) Section II(a) of the PPA closely tracks Section 602 of the Veterans Health Care Act of 1992, which was enacted to "require a manufacturer to extend the same price reduction to a covered entity for a drug or biological as is provided under the Medicaid outpatient drug rebate program." *Joint Explanatory Statement on H.R. 5193*, 138 Cong. Rec. S17890, 1992 U.S.C.C.A.N. 4186, 4211. Its purpose was "to *enable . . . certain Federally-funded clinics [i.e., covered entities] to obtain lower prices* on the drugs that they provide to their patients" by prohibiting "Medicaid matching funds [from being] available for State spending on[a manufacturer's covered drugs] unless the manufacturer enters into, and *complies with*, an agreement . . . . under which these protected purchasers [e.g., covered entities] would pay the same amount for a covered outpatient drug that Medicaid pays." H.R.Rep. No. 102-384(II), at 7-8 (1992) (emphasis added). "In giving these 'covered entities' access to price reductions the Committee intends to *enable these entities* to stretch scarce Federal resources as far as

possible, reaching more eligible patients and providing more comprehensive services." *Id.* at 12 (emphasis added). Thus, although we agree with the Manufacturers that § 256b's general purpose is to "conserve federal resources so as to reach as many eligible patients as possible," the legislative history makes plain that Congress intended to accomplish this objective by enabling covered entities (and other "protected" purchasers, a revealing choice of words) to obtain discounted prices on covered drugs through the PPAs.[9]

Relying on *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir.1985), the Manufacturers contend that the PPA's provision of an "elective" or "informal" dispute resolution process means the parties intended to preclude third party enforcement of the contract by the covered entities. Sections IV(a), (b) and (d) of the PPA allow manufacturers to refer certain disputes they have with covered entities to the Secretary to conduct an investigation. If the Secretary then finds that the covered entity is in violation, he may impose monetary liability or remove the entity from the list of eligible entities.[10] Conversely, if the Secretary believes a

9. Protected purchasers also include the Department of Veterans Affairs, the Department of Defense, the Public Health Service and the Indian Health Service. *See* Veterans Health Care Act of 1992 § 603(a), Pub.L. No. 102-585, 106 Stat. 4943, 4972 (codified at 38 U.S.C. § 8126(b)); H.R.Rep. No. 102-384(II), at 7-8.

10. The informal dispute resolution remedies against the covered entities run through the Secretary, who has the power

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manufacturer has overcharged covered entities, he may initiate an "informal dispute resolution process," which could result in the covered entities being reimbursed and the manufacturer's PPA being terminated. *See* PPA § IV(c). The Manufacturers also cite DHHS's regulations, which, apart from the PPA, establish a "voluntary process for the resolution of certain disputes between manufacturers and covered entities concerning compliance with the provisions" of § 256b. *See* Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed.Reg. 65,406-01, 65,411-13 (Dec. 12, 1996). This process is also voluntary: "Covered entities or manufacturers are not required to enter this informal process for resolution of disputes. . . ." *Id.* at 65,411.

*D'Amato* does not support the Manufacturers' argument. There, the plaintiffs attempted to bring suit as third party beneficiaries of affirmative action provisions whose inclusion in procurement contracts was required by Section 503 of the Rehabilitation Act of 1973. As a threshold matter, the contracts themselves suggested that the plaintiffs were not intended beneficiaries; they were "not directed at the

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to "establish a mechanism to ensure that covered entities comply" with the Section 340B program's requirements and sanction them for noncompliance. *See* § 256b(a)(5)(A)(ii), (D). We construe these PPA provisions as simply restating the covered entities' statutory obligations, because as a matter of federal common law, even a third party beneficiary "cannot be bound to a contract it did not sign." *See Comer v. Micor, Inc.*, 436 F.3d 1098, 1102 (9th Cir.2006).

handicapped in any way but instead focus[ed] exclusively on the government—contractor relationship." *D'Amato*, 760 F.2d at 1479. The court found *further* support for its conclusion that the disabled were not intended beneficiaries in Section 503 and its implementing regulations, which established an administrative remedy for any "handicapped individual [who] believe[d] any contractor has failed . . . to comply" with the affirmative action provisions and emphasized the resolution of disputes "by informal means, including conciliation[ ] and persuasion." *See id.* at 1477 n. 1, 1481-82 (citing 29 U.S.C. § 793(b) and 41 C.F.R. § 60-741.28(a) (1984)).

We perceive four material differences between the contract and statute in *D'Amato* and those here. First, as discussed above, the PPA sets forth the contracting parties' clear intent to directly benefit the covered entities. *Cf. id.* at 1479-80. Second, § 256b says nothing about the covered entities' remedies, whether judicial or administrative. *Cf. id.* at 1481 ("The statutory grant of *one* remedy . . . without mention of any other . . . . implies that Congress intended to bar *other* remedies.") (emphasis added). Third, allowing covered entities to bring suit as third party beneficiaries would not conflict with the PPA's informal dispute resolution process, given that the entities themselves are unable to initiate that process.[11] Last, the voluntary administrative dispute

11. *Cf. FMC Corp.*, 531 F.3d at 823 (declining to recognize intended beneficiary status because that would "grant a broader range of dispute—resolving rights to [third parties] than to the [contracting] parties," who were required to exhaust the

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resolution procedure created by DHHS's regulations expressly leaves open resort to "other remedies which may be available under applicable principles of law." *See* 61 Fed.Reg. at 65,412; *see also id.* at 65,411 ("[Covered] entities are only encouraged to participate in the process before seeking other remedies."). In sum, neither the PPA nor § 256b establishes an exclusive "elaborate administrative procedure," *D'Amato*, 760 F.2d at 1482, that—were such a procedure to exist-would signal the parties' intent to deny covered entities the right to enforce the PPA through litigation as intended beneficiaries.

The Manufacturers' remaining arguments against the covered entities' intended beneficiary status are no more convincing. First, they contend it is "illogical" that the United States and the Manufacturers would have intended to expose themselves to suit by the large number of covered entities, about 13,000 reported as of this writing.[12] The breadth and indefiniteness of a class of beneficiaries is entitled to some weight in negating

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contract's "prescribed dispute resolution mechanisms" before bringing suit). By contrast, the PPA provides that its informal dispute resolution process will not "preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law." *See* PPA § IV(e).

12. *See* Department of Health and Human Services, Office of Pharmacy Affairs, *Growth of 340B Covered Entity Sites From 01/1998 to Present*, http:// opanet. hrsa. gov/ opa/ Report/ Statistical Report. aspx.

the inference of intended beneficiary status. *See Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir.1987) (commenting that parties would not likely have intended that "almost every lower-income person in the United States" could enforce the contract). But numbers alone are not determinative. For example, in *Hook v. State of Ariz., Dep't of Corr.*, 972 F.2d 1012, 1014-15 (9th Cir.1992), we recognized all inmates of the Arizona prison system as intended beneficiaries of a consent decree regulating mail policies. Similarly in this case, covered entities constitute a narrow, well-defined class, not at all akin to members of the public at large. *See* § 256b(a)(4) (defining "covered entity"); PPA § III(a) (making available list of eligible covered entities), § IV(b) (procedure for challenging eligibility of covered entities).

We are also unmoved by the Manufacturers' protest that they "surely would not have agreed to subject themselves to a large number of lawsuits that could undermine the confidentiality" of pricing data through discovery, given the PPA's inclusion of a confidentiality provision.[13] The confidentiality provision itself, however,

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13. This argument is problematic for another, more pragmatic reason, which is that the PPA was not a conventionally negotiated contract. Presumably, the Manufacturers would have preferred not to give covered entities any discount at all, but they faced an overwhelmingly powerful incentive to accept the PPA. Eligibility for a number of substantial federal healthcare programs is conditioned on having an effective § 256b agreement with the Secretary. *See* § 1396r-8(a)(1), (a)(5)(A); *see generally Joint Explanatory*

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contemplates that such information could well be subject to disclosure for purposes of enforcing the PPA's discount pricing requirements beyond any actions the Secretary might initiate. Section V(a) specifies that information disclosed to the Secretary by the Manufacturers, "*except as otherwise required by law,* will not be disclosed *by the Secretary or his designee* in a form which reveals the Manufacturer, except as necessary to carry out the provisions of [§ 256b] and to permit review by the [OIG]." (Emphasis added.) As the italicized phrases highlight, the confidentiality provision anticipates that disclosures could be required other than to or by the Secretary. A district court's discovery order compelling the production of documents would be a disclosure "required by law"; and it would be the manufacturer, not the Secretary, disclosing the information. To the extent a drug company would rightly be concerned about sensitive pricing information, district courts routinely enter protective orders to prevent the undue disclosure of commercially sensitive information. *See* Fed.R.Civ.P. 26(c); *Phillips ex rel. Estates of Byrd v. Gen. Motors Corp.*, 307 F.3d 1206, 1210-12 (9th Cir.2002). Thus we are unwilling to read the PPA's confidentiality proviso as negating third party

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*Statement on H.R. 5193*, 138 Cong. Rec. S17890, 1992 U.S.C.C.A.N. 4186, 4211 (explaining that § 256b makes the "use of federal matching funds for payment for a covered outpatient drug [by State Medicaid programs] . . . contingent on . . . a manufacturer's entering into [ ] an agreement . . . under which the manufacturer agrees to provide rebates or discounts to" covered entities).

covered entities' right to enforce the discount pricing requirements themselves.

## II.

Although we conclude that covered entities are intended beneficiaries of the PPA, and so would ordinarily be entitled to bring suit to enforce it, the Manufacturers urge that this is not the usual intended beneficiary case and that permitting third party enforcement of the PPA would conflict with Congress' intent in creating the Section 340B program.[14] In this vein, they point to Santa Clara's concession before the district court that there is no private federal cause of action under § 256b.[15] *See generally Alexander v. Sandoval*, 532 U.S. 275, 121 S.Ct. 1511, 149 L.Ed.2d 517 (2001). Because Congress did not provide a *statutory* remedy, the Manufacturers argue, it necessarily did not intend to allow covered entities to make an "end-run" around the statutory scheme by pursuing *contractual* remedies under the federal common law.

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14. Although this argument was raised for the first time in the Manufacturers' reply to Santa Clara's opposition to its motion to dismiss and the district court did not address it, we will pass on the merits here. The issue is one of law and has been fully briefed by both parties. *See Pocatello Educ. Ass'n v. Heideman*, 504 F.3d 1053, 1060 n. 5 (9th Cir.2007); *Bibeau v. Pac. Northwest Research Foundation Inc.*, 188 F.3d 1105, 1111 n. 5 (9th Cir.1999).

15. Santa Clara has not pursued this matter on appeal, so we assume without deciding that § 256b does not create a private cause of action.

The starting point of this argument is the truism that federal common law, of which the federal common law of contracts forms a part, "is 'subject to the paramount authority of Congress.'" *City of Milwaukee v. Illinois & Michigan*, 451 U.S. 304, 313, 101 S.Ct. 1784, 68 L.Ed.2d 114 (1981) (quoting *New Jersey v. New York*, 283 U.S. 336, 348, 51 S.Ct. 478, 75 L.Ed. 1104 (1931)). We presume that Congress legislates with the expectation that the principles of the federal common law "will apply except 'when a statutory purpose to the contrary is evident.'" *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 108, 111 S.Ct. 2166, 115 L.Ed.2d 96 (1991) (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783, 72 S.Ct. 1011, 96 L.Ed. 1294 (1952)). However, when Congress "speak[s] directly" to a question addressed by the federal common law, it may displace it even without "affirmatively proscrib[ing]" its use. *United States v. Texas*, 507 U.S. 529, 534, 113 S.Ct. 1631, 123 L.Ed.2d 245 (1993); *see also Gardiner v. Sea-Land Service, Inc.*, 786 F.2d 943, 947 (9th Cir.1986). "In evaluating the displacement issue, courts must assess the scope of the legislation and whether the legislative scheme addresses the problem formerly governed by federal common law." *Gardiner*, 786 F.2d at 947.[16] The Manufacturers, relying almost exclusively

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16. This is a different and less demanding inquiry than that used to evaluate whether a federal statute preempts a state-law cause of action, *see City of Milwaukee*, 451 U.S. at 316-17, 101 S.Ct. 1784; *cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996), or whether a federal statute's comprehensive remedial scheme impliedly displaces (Cont'd)

on *Grochowski v. Phoenix Constr.*, 318 F.3d 80 (2d Cir.2003), contend that § 256b does just that and, therefore, to allow covered entities to enforce the PPA as a matter of contract would be inconsistent with Congress' choice of remedies.

In *Grochowski*, the Second Circuit did not permit the plaintiffs to bring suit as third party beneficiaries of a contract between the contractor defendants and New York City's public housing authority. *See* 318 F.3d at 83. Under the Davis-Bacon Act, 40 U.S.C. § 3141, all construction contracts for federally funded projects must include the following provision: "[t]he Contractor shall pay to all laborers . . . not less than the wages prevailing in the locality of the Project, as predetermined by the Secretary of Labor of the United States." *Id.* (first alteration in original). Exercising his authority under 40 U.S.C. § 3145 to "prescribe reasonable regulations for contractors" subject to the

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a more general federal private cause of action such as 42 U.S.C. § 1983, *see Middlesex County Sewerage Auth. v. Nat'l Sea Clammers Ass'n*, 453 U.S. 1, 20-21, 101 S.Ct. 2615, 69 L.Ed.2d 435 (1981); *Flores v. Arizona*, 516 F.3d 1140, 1174-75 (9th Cir.2008). *See generally Resolution Trust Corp. v. Frates*, 52 F.3d 295, 296-97 (10th Cir.1995) (explaining difference between preemption of state law and supersession of the federal common law). We conclude that § 256b does not abrogate the cause of action ordinarily provided by the federal common law of contracts; thus it does not preempt a state-law contract cause of action, if that indeed is how Santa Clara's claim should be characterized. *See supra* note 5.

Davis-Bacon Act, the Secretary of Labor established an administrative remedial scheme. *See id.* at 85; *Chan v. City of New York*, 1 F.3d 96, 102 (2d Cir.1993) (citing 29 C.F.R. §§ 1.8, 5.6(a)(3), 5.11). Given these administrative remedies, and the absence of an explicit private cause of action, *Grochowski* concluded that the "plaintiffs['] efforts to bring their claims as state common-law [contract] claims [were] clearly an impermissible 'end run'" around congressional intent as to the availability of remedies under the Davis-Bacon Act. 318 F.3d at 86.

Assuming *Grochowski* was correctly decided, the case is clearly inapposite on its own terms.[17] Its analytical under-pinning was the "'elemental canon' of statutory construction that where a *statute expressly provides a remedy*, 'courts must be especially reluctant to provide *additional* remedies.'" *Id.* at 85 (quoting *Karahalios v. Nat'l Fed'n of Employees, Local 1263*, 489 U.S. 527, 533, 109 S.Ct. 1282, 103 L.Ed.2d 539 (1989)) (emphasis added). Here, § 256b does not "expressly provide" any remedies to covered entities.[18] And unlike the Davis-

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17. Because the *Grochowski* plaintiffs' contract claims were based on state law, not federal law, it is puzzling that the majority did not frame its analysis in terms of whether Congress intended to preempt those claims. *See, e.g., Grochowski*, 318 F.3d at 90-91 (Lynch, J. dissenting); *Cox v. NAP Constr. Co., Inc.*, 10 N.Y.3d 592, 603-07, 861 N.Y.S.2d 238, 891 N.E.2d 271 (N.Y.2008).

18. Section 256b does provide a number of remedies *against* covered entities. *See, e.g.*, § 256b(a)(5)(C) ("A covered entity shall permit the Secretary and [manufacturers] . . . to

(Cont'd)

Bacon Act, § 256b is silent about the agency's power to promulgate regulations against *manufacturers* with the force of law. *Cf.* § 256b(a)(5)(A)(ii) ("The Secretary shall establish a mechanism to ensure that *covered entities* comply . . . .") (emphasis added). Although the Secretary may terminate the PPA with a manufacturer for a violation of its provisions, this remedy is a matter of contract, not statute. *See* PPA § VI(c). Reflecting this paucity of statutory authority, DHHS's regulations establish only an informal, nonexclusive dispute resolution process, in which neither covered entities nor manufacturers are required to participate. *See* 61 Fed.Reg. at 65,411. Nothing in the statute suggests that Congress intended that DHHS create a substitute, administrative remedial scheme for covered entities to invoke against manufacturers. Thus, there is nothing "additional" about the federal common law contract remedy that the covered entities could invoke as intended beneficiaries of the PPA. *Cf. Golt v. United States*, 186 F.3d 1158, 1164 (9th Cir.1999) (holding that Civil Service Reform Act, which expressly created exclusive administrative remedy, abrogated remedies under federal common law).

Permitting covered entities to sue as intended beneficiaries of the PPA is therefore wholly compatible with the Section 340B program's objectives. *Cf. Trimble*

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(Cont'd)

audit . . . records of the entity that directly pertain to the entity's compliance" with the program.); (a)(5)(D) ("If the Secretary finds . . . that a covered entity is in violation . . . the covered entity shall be liable. . . .").

*Navigation*, 484 F.3d at 707 ("[R]ecognition of third-party beneficiary status in a contract made under a statutory scheme must accord with that scheme. . . ."); Restatement (Second) of Contracts § 313(1) (1981) (limiting application of third party beneficiary doctrine when it "would contravene the policy of the law authorizing the contract or prescribing remedies for its breach"). As we have explained, the Section 340B program was created to give covered entities discounts so they could "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R.Rep. No. 102-384(II), at 12 (1992). Federal common law contract remedies are one way of ensuring that drug companies comply with their obligations under the program and provide those discounts. *See Price*, 823 F.2d at 1121 (observing that it "seemed more sensible" to permit third parties to sue as intended beneficiaries than to "place the entire burden of enforcement" on the government).

## III.

Finally, we hold that the doctrine of primary jurisdiction does not require that Santa Clara's contract claim be stayed or dismissed without prejudice pending its referral to the Secretary for agency resolution. The doctrine of primary jurisdiction "is a prudential doctrine under which courts may, under appropriate circumstances, determine that the initial decisionmaking responsibility should be performed by the relevant agency rather than the courts." *Syntek Semiconductor*

*Co., Ltd. v. Microchip Tech. Inc.*, 307 F.3d 775, 780 (9th Cir.2002). "[P]rimary jurisdiction is properly invoked when a claim is cognizable in federal court but requires resolution of an issue of first impression, or of a particularly complicated issue that Congress has committed to a regulatory agency." *Id.* (quoting *Brown v. MCI WorldCom Network Servs., Inc.*, 277 F.3d 1166, 1172 (9th Cir.2002)). The doctrine does not require that all claims touching on an agency's expertise first be decided by the agency, however. *See id.* "The particular agency deferred to must be one that Congress has vested with the authority to regulate an industry or activity such that it would be inconsistent with the statutory scheme to deny the agency's power to resolve the issues in question." *United States v. Culliton*, 328 F.3d 1074, 1082 (9th Cir.2003) (internal quotation marks omitted). To determine whether primary jurisdiction should be applied, we have "employed such factors as (1) the need to resolve an issue that (2) has been placed by Congress within the jurisdiction of an administrative body having regulatory authority (3) pursuant to a statute that subjects an industry or activity to a comprehensive regulatory authority that (4) requires expertise or uniformity in administration." *Syntek*, 307 F.3d at 781.

In our view, there is nothing "particularly complicated" about Santa Clara's contract claim on the merits.[19] Santa Clara alleges that the Manufacturers did

19. Although the issue of whether covered entities are entitled to sue as third party beneficiaries of the PPA is by no means straightforward, DHHS's regulatory authority does not (Cont'd)

not comply with their obligation under the PPA to charge covered entities a price that "does not exceed . . . the [average manufacturer price] for the [covered drug] *reported* . . . . to the Secretary in accordance with the Manufacturer's responsibilities under [§ 1396r-8(b)(3) ] . . . reduced by the rebate percentage." *See* PPA § II(a) (emphasis added). Contrary to the Manufacturers' suggestion, resolution of this claim presents no "far-reaching question that 'requires expertise or uniformity in administration.'" *Cf. Brown*, 277 F.3d at 1172. The PPA is drafted, for instance, so that covered entities are entitled only to the average manufacturer price *reported* to the Secretary; they cannot claim that the reported figure was itself somehow erroneous.[20] Moreover, when a covered entity sues a manufacturer for failing to comply with its ceiling price obligations under the PPA, but "'does not seek to impose any additional or contrary obligations[,] [it] is merely enforcing the existing rebate program responsibilities and does not inject any more variation than if the Department of Justice brought suit.'" *See generally Massachusetts v. Mylan Labs.*, 357 F.Supp.2d 314, 329 (D.Mass.2005) (quoting amicus brief of the United States filed in suit brought by states to enforce

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(Cont'd)
extend to the federal common law of contracts, so we have no occasion to defer to the agency's expertise in deciding this appeal.

20. We do not decide whether the PPA's "reporting" limitation is consistent with § 256b(a)(1)'s requirements for pharmaceutical purchasing agreements.

Medicaid State Rebate Agreement).[21] We do not understand Santa Clara's complaint as taking issue with the agency's established guidance for calculating prices under § 1396r-8, so we conclude that its contract claim does not implicate DHHS's primary jurisdiction.

## CONCLUSION

As intended direct beneficiaries of the PPA, covered entities may enforce the Manufacturers' ceiling price obligations under the federal common law of contracts. Although the statute mandating the PPA does not create a federal private cause of action, allowing Santa Clara's contract claim to go forward is consistent with Congress' intent in enacting the legislative scheme. Because it lies within the conventional competence of the courts, that claim is not within the primary jurisdiction of DHHS.

**REVERSED and REMANDED.**

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21. The relationship between states and manufacturers under the Medicaid State Rebate Agreement is roughly analogous to that between covered entities and manufacturers under the PPA. Neither party requested that the district court or we seek the views of the Secretary of Health and Human Services as amicus curiae.

## APPENDIX C — ORDER REGARDING DISCOVERY AND DENYING DEFENDANTS' MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA FILED MARCH 19, 2010

**UNITED STATES DISTRICT COURT**
**NORTHERN DISTRICT OF CALIFORNIA**

**No. C 05-03740 WHA**

THE COUNTY OF SANTA CLARA and
THE COUNTY OF SANTA CRUZ,

Plaintiffs,

v.

ASTRA USA, INC., et al.,

Defendants.

March 19, 2010

WILLIAM ALSUP, District Judge.

### ORDER REGARDING DISCOVERY AND DENYING DEFENDANTS' MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS

*Appendix C*

## INTRODUCTION

In this action, two California counties allege that defendant pharmaceutical firms overcharged them by charging prices for drugs greater than the ceiling price imposed by Section 340B of the Public Health Service Act of 1992 and contractual agreements thereunder. After multiple trips to the court of appeals, the immediate issue concerns discovery, namely the extent to which plaintiffs may discover data behind the numbers reported to the federal agency so as to try to prove overcharges. All defendants now move for partial judgment on the pleadings, or in the alternative, a protective order. Defendant Bristol-Myers Squibb moves individually for a stay on primary jurisdiction grounds, or in the alternative, for a protective order. Defendants AstraZeneca and Bayer move for a protective order, or in the alternative, for a stay of discovery. Plaintiffs filed a cross-motion to compel discovery. For the following reasons, defendants' motion for partial judgment on the pleadings is **DENIED**. The stay motions are **DENIED**. Discovery will proceed as to all defendants, except as to Bristol-Myers Squibb. As to it, discovery will proceed more slowly. Complete compliance with *all* of plaintiffs' requests, however, will not be required at this time. Instead, discovery will proceed in stages. This order lists the discovery to be produced in the first stage.

*Appendix C*

## STATEMENT

Plaintiff County of Santa Clara owns and operates the Santa Clara Valley Health and Hospital System. Plaintiff County of Santa Cruz owns and operates the Santa Cruz County Health Agency. Plaintiffs allege that defendant pharmaceutical manufacturers breached contractual duties owed to plaintiffs as third-party beneficiaries of the agreements between the manufacturers and the Secretary of the Department of Health and Human Services called the Pharmaceutical Pricing Agreements ("PPAs").

The PPAs carry out statutory obligations that arise under Section 340B of the Public Health Service Act of 1992. 42 U.S.C. 256b. Congress passed Section 340B to provide discounts on outpatient drugs to certain federally-funded hospitals and clinics— so-called "covered entities." The Act mandates that the Secretary:

> enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C. 1396r-8(k)(1)] . . . reduced by the rebate percentage described in paragraph (2).

42 U.S.C. 256b(a)(1). Under this agreement, the manufacturers may not charge any 340B entities over the so-called "ceiling price" created by the statute.

Acting pursuant to Section 340B, the Secretary entered into PPAs with drug manufacturers, including defendants. Section II(a) of the PPA stated (Compl. Exh. D at 5) (emphasis added):

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:
>
> (a) for single source and innovator multiple source drug, to charge covered entities a price for each unit of the drug *that does not exceed an amount equal to the AMP for the covered outpatient drug reported* (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) *to the Secretary in accordance with the Manufacturer's responsibilities under action 1927(b)(3)* of the Social Security Act, reduced by the rebate percentage.

In this civil action, plaintiffs contend that defendants violated their obligations under the PPA by charging a price exceeding the ceiling price defined in Section 340B and the PPA.

*Appendix C*

The *amicus* brief filed in the most recent appeal on behalf of the Secretary explained the interplay between two programs of the Department of Health and Human Services ("HHS") (Br. 7). The first is the Medicaid Rebate Program, which is administered by the Centers for Medicare Services ("CMS"). The second is the 340B Program, which is administered by the Health Resources and Services Administration ("HRSA").

The 340B Program, governed by 42 U.S.C. 256b, is the basis for plaintiffs' complaint. Under it, so-called "ceiling prices" are calculated using average manufacturer price ("AMP") and best price ("BP"). The AMPs and BPs are originally calculated in accordance with the requirements of a separate and preexisting HHS program: the Medicaid Rebate Program.

Under the Medicaid Rebate Program, pharmaceutical manufacturers are required to sign a Medicaid Rebate Agreement with HHS in order for a state to receive federal payment for coverage of outpatient drugs (Br. 2). The agreement requires that the manufacturers pay drug rebates to the states. In order to determine the amount of rebates for a given drug, the number of "units" of the drug paid for by the state is multiplied by the drug's "Unit Rebate Amount" ("URA"). The URA is calculated in several different ways. For a "generic drug," the URA is 11% of the AMP. For a "single-source" drug, the URA is the *greater* of two calculations: (1) AMP - BP = URA; or (2) 15.1% of the AMP (*id.* at 3).

*Appendix C*

According to the Social Security Act, average manufacturer price is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade." 42 U.S.C. 1396r-8(k)(1)(A). The best price is defined as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States" and lists several exclusions. 42 U.S.C. 1396r-8(c)(1)(C). Under the Medicaid Rebate Program, manufacturers must make calculations of AMP and BP every quarter and are required to report the calculated numbers to CMS within thirty days after the end of each quarter (Br. 4). Using these figures, CMS calculates the URA for each drug. The URA amount is sent to each state to enable them to calculate their quarterly rebate amount.

Although separate from the Medicaid Rebate program, the 340B program incorporates the AMP and URA values (and thus, BP values) in the formula for determining the ceiling prices. As stated, the PPAs required under Section 340B ensure that manufacturers may not charge any "covered entity" a price that exceeds the ceiling price. The simplified formula for the 340B ceiling price is: Ceiling Price = AMP - URA. *Once the ceiling price for a certain drug is determined, it is the ceiling for all of the 340B covered entities.*

Although the 340B program is enforced by the HRSA, it does so with "significant help" from CMS

(Br. 9). This is "because ceiling prices depend on the AMP and Best Price calculations that manufacturers report to CMS under the Medicaid Rebate Program" (*ibid.*). Pursuant to inter-agency agreements, after being reported to CMS, the AMP and BP data is provided to HRSA for use in the Section 340B program.

Plaintiffs allege that each defendant breached the PPA by overcharging for covered drugs. Plaintiffs sued in state court in August 2005, and the case was removed to federal court. Defendants moved to dismiss all claims in the second amended complaint for failure to state a claim. The motion was granted in May 2006.

On appeal, however, the court of appeals ruled that plaintiffs *were* third-party beneficiaries of the PPA and therefore may proceed with their contract claim. *County of Santa Clara v. Astra USA, Inc.*, 540 F.3d 1094 (9th Cir. 2008) ("*Santa Clara I*"). On remand, a case management conference was held. The parties were directed to proceed with discovery. Defendants thereafter moved for a protective order, stating that plaintiffs were not entitled to discovery into the underlying data utilized by drug manufacturers to calculate the AMP and URA (*i.e.*, the data used to calculate the components of the ceiling price), but only to the AMPs and BPs actually reported. The motion was granted based on a sentence in the appellate decision, but the protective order was certified for interlocutory appeal to make sure the sentence was really intended by the circuit judges. Last December, the Ninth Circuit modified its earlier order to eliminate the offending

sentence and vacated the protective order. *County of Santa Clara v. Astra USA, Inc.*, 588 F.3d 1237 (9th Cir. 2009) ("*Santa Clara II*"). On the latest remand, discovery was reopened to allow plaintiffs to take discovery regarding the information underlying defendant manufacturers' determination of AMP and BP.

To head off the very discovery that seemed indicated by the remand, defendants now move for partial judgment on the pleadings, or in the alternative, for a protective order. Defendants Bristol-Myers Squibb, Bayer, and AstraZeneca also move individually for protective orders and/or request a stay of discovery. Plaintiffs move to compel defendants' production of documents and information responsive to plaintiffs' discovery requests.

## ANALYSIS

### 1. MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS.

Under Rule 12(c), "[a]fter the pleadings are closed but within such time as not to delay the trial, any party may move for judgment on the pleadings." A motion for judgment on the pleadings is evaluated according to virtually the same legal standard as a motion to dismiss under Rule 12(b). *Brennan v. Concord EFS, Inc.*, 369 F. Supp. 2d 1127, 1130-31 (N.D. Cal. 2005). "Judgment on the pleadings is proper when the moving party clearly establishes on the face of the pleadings that no material

issue of fact remains to be resolved and that it is entitled to judgment as a matter of law." *Hal Roach Studios, Inc. v. Richard Feiner and Co*, 896 F.2d 1542, 1550 (9th Cir. 1990). Moreover, "[a]ll allegations of fact by the party opposing the motion are accepted as true, and are construed in the light most favorable to that party." *General Conference Corp. of Seventh-Day Adventists v. Seventh-Day Adventist Congregational Church*, 887 F.2d 228, 230 (9th Cir. 1989).

All defendants move for partial judgment on the pleadings on the ground that "plaintiffs have failed to state a claim regarding miscalculations of average manufacturer price and best price" and assert that plaintiffs must "at least be ordered to amend their pleadings" (Br. 1).

All defendants first argue that plaintiffs have not pled facts sufficient to allege a plausible claim for relief as to AMP and BP under *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009), and *Twombly v. Bell Atlantic Corp.*, 550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). Under the *Iqbal-Twombly* standard for a Rule 12(b)(6) motion to dismiss, a complaint needs to be plausible, meaning that "the plaintiff [must] plead[ ] factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 129 S. Ct. at 1949. All defendants argue that because plaintiffs fail to allege the *nature* of the miscalculations of AMP and BP as to each defendant, that the complaint fails to meet the pleading standard.

The Ninth Circuit, however, has found that plaintiffs' contract claim can proceed, and therefore meets the pleading standard to survive a motion to dismiss. Plaintiffs have already demonstrated that in order to determine the actual nature of the miscalculations, they must have access to the information used in the original calculations of the AMPs and BPs. The court of appeals acknowledged that "[a]t this stage, the nature of the breaches Santa Clara will seek to prove is unclear . . .". *Santa Clara II*, 588 F.3d at 1252. The revised opinion recognized that the complaint was lacking a full description of the alleged breach. Regardless of this potential shortcoming, the claim for breach of contract was determined to have survived the Rule 12(b)(6) standard. Accordingly, the mere fact that plaintiffs have not alleged the specific nature of the breach does not preclude them from meeting the pleading standard under Rule 12(c).

All defendants also argue that discovery should be barred because it would violate the confidentiality provisions of the Social Security Act. The court of appeals was "unmoved" by defendants' original argument to bar disclosures under the PPA confidentiality provision. *Santa Clara II*, 588 F.3d at 1248. The wording of the PPA confidentiality provision and the relevant portion of the Social Security Act are materially similar. The Act states:

> information disclosed by manufacturers . . . under this paragraph or under an agreement with the Secretary of Veterans Affairs

> described in subsection (a)(6)(A)(ii) of this section . . . is confidential and shall not be disclosed by *the Secretary* . . . in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler . . .

42 U.S.C. 1396r-8(b)(3)(D) (emphasis added). The PPA similarly stated: "[i]nformation disclosed by the Manufacturer in connection with the Agreement, except as otherwise provided by law, will not be disclosed by *the Secretary* . . . in a form which reveals the Manufacturer . . ." (Compl. Exh. D at 8) (emphasis added). The Ninth Circuit determined that "the confidentiality provision [of the PPA] anticipates that disclosures could be required other than to or by the Secretary." Just as with the PPA, "it would be the manufacturer, not the Secretary, disclosing the information" and the disclosures would therefore not be barred by the confidentiality obligations of the Act. *Santa Clara II*, 588 F.3d at 1249. Just as the Ninth Circuit was unwilling to accept defendants' confidentiality argument with regard to the PPA, this order declines to find the almost-identical Social Security Act provision prohibitive of plaintiffs' ability to pursue their claim for breach of contract.

Lastly, defendants argue that discovery should be deferred until the Ninth Circuit rules on the pending petition for panel rehearing and rehearing *en banc*. Defendants' petition was denied on February 12, 2010

(Dkt. 586). It is therefore unnecessary for this order to address defendants' argument for deferral on these grounds.

For all of the above-stated reasons, defendants' joint motion for partial judgment on the pleadings is **DENIED**. Defendants' joint request that plaintiffs be required to amend their pleadings is also **DENIED**.

2. **MOTIONS TO STAY**.

Defendants AstraZeneca, Bayer, and BMS have requested a stay of discovery. These defendants argue that the discovery sought by plaintiffs implicates the primary jurisdiction of the HHS. Additionally, BMS makes an individual argument for their motion to stay, asserting that after their individual cooperative review, HHS reserved jurisdiction over "additional adjustments or revisions" (Br. 17).

The Ninth Circuit specifically rejected primary jurisdiction as a show stopper to this case. The court of appeals, however, did "leave open the possibility that the district court may decide after further factual development that referral to the Secretary is appropriate." *Santa Clara II*, 588 F.3d at 1252. After further discovery and factual development it may be proper to refer this case to the HHS. At this time, however, before discovery as to the AMP and BP calculations has been allowed, the "factual development" contemplated by the Ninth Circuit has not been established. The government's *amicus* brief filed on

appeal also agrees that primary jurisdiction is not necessary at this point (Br. 14). Accordingly, the individual defendants' motions to stay are **DENIED.**

## 3. DISCOVERY.

### A. Motions for Protective Order.

Along with the joint motion for partial judgment on the pleadings, all defendants also presented argument for a protective order to prevent discovery regarding the underlying information used to calculate AMP and BP.

Under Rule 26(c), "[t]he court may, for good cause, issue an order to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense . . . ." All defendants have two arguments in support of a protective order. The first is that case management would be served if plaintiffs were required to further articulate their claim and assert the nature of the AMP and BP miscalculations that led to the alleged breach. The argument continues that without such a limitation, plaintiffs' requests will amount to "fishing expedition" and will require the production of such a mass of information as to be unduly burdensome. The appellate court's most recent statement flat-out called for "further factual development" and the only practical way to do so is via discovery. *Santa Clara II*, 588 F.3d at 1252. This order will not require plaintiffs to amend their pleadings to further articulate their claim. The undersigned,

however, will consider the possible burden on defendants when determining appropriate limitations on discovery.

Defendants Bayer, and AstraZeneca filed individual motions for protective orders. They argue that since they complied with the terms of the Corporate Integrity Agreement ("CIA") and were overseen by the HHS through this agreement, the discovery is irrelevant because plaintiffs may not second-guess HHS' approval and oversight of the AMP and BP calculations. Under the terms of the CIA, defendants were audited on a yearly basis by a independent review organization ("IRO"). Defendants AstraZeneca and Bayer contend "Plaintiffs requested discovery would merely repeat the intensive oversight and analysis that HHS has already undertaken through the CIAs, allowing Plaintiffs to substitute their biases for the judgment and expertise of HHS" (Br. 4). These defendants argue that allowing discovery would be allowing plaintiffs to second-guess the HHS, which "Plaintiffs have no right to do" (*ibid.*). Until we know the facts and know the extent to which HHS knew everything it should have known, it is premature to say that we will wind up second-guessing anybody in this case. Accordingly, this order will not enter a protective order on those grounds and the motion by AstraZeneca and Bayer is **DENIED**.

Defendants Bristol-Myers Squibb ("BMS") also filed an individual motion for protective order. BMS asserts an individual argument that plaintiffs' requests are especially burdensome in its case because of the cooperative review with HHS that was conducted to

revise hundreds of BMS' AMPs and BPs (Br. 3). BMS contends that plaintiffs' document requests would call for thousands of communications, many of them privileged, that were produced in connection with the review. BMS' request for a protective order is **GRANTED**, subject to the provisos below.

**B. Plaintiffs' Cross-Motion to Compel.**

Plaintiffs have filed a cross-motion to compel. Plaintiffs' motion is based on the same arguments set forth in the opposition to defendants' motions for a protective order. These arguments have been discussed above, and need not be addressed again. As to the motion to compel, this order reaches the same result discussed above. The undersigned will allow for discovery to proceed, however, complete production of documents responsive to all plaintiffs' requests will not be required at this time. In their motion, plaintiffs suggest several methods of limiting discovery including (Br. 5):

> (a) where there are a large number of drugs at issue, plaintiffs have offered to limit the discovery to only the top 25% of the drugs sold to Santa Clara and Santa Cruz for those manufacturers who sold over 100 drugs to 340B entities; and (b) plaintiffs have offered to limit the textual documents to be searched by agreeing to a sequencing of the production and by further agreeing to a list of custodians and search terms in advance of the search for textual documents.

This order will adopt some variations on these limitations.

**C. First Stage of Discovery.**

In order to facilitate further factual development while continuing to monitor the potential burden on defendants in complying with the entire list of requested discovery, this order will allow for further discovery in stages. Defendants must produce information and documents from the start of the limitations period (August 16, 2001) to the date of the filing of the third amended complaint (December 23, 2008). In this first stage of discovery, defendants must produce the following:

> 1. All information responsive to plaintiffs' interrogatories numbers 1 through 4, regarding information underlying defendant manufacturers' determinations of AMP and BP. Request number 5 is rejected as overbroad and unduly burdensome.
>
> 2. All quarterly and monthly or other periodic reports of AMP and BP filed with CMS, if not already produced.
>
> 3. All work papers prepared or used by defendants or their agents or consultants in preparation of AMP or BP.

4. All communications and audits with or by CMS or IROs concerning the accuracy of AMPs and BPs in said reports.

5. All summaries and/or descriptions of guidelines or standard procedures or methods to be used by the defendants to prepare the quarterly reports to CMS.

6. Documents sufficient to identify the National Drug Codes for covered drugs with respect to which defendants were responsible for reporting AMPs and BPs to CMS.

7. Documents including organization charts, sufficient to show defendants' management structure and hierarchy and the positions and individuals responsible for or involved in determining AMP, BP and URA.

8. All materials explaining how the computer tracking systems worked to flag and determine the AMP and BP.

9. All invoices and other data necessary to verify the accuracy (or not) of the AMP and BP for the top three drugs sold by each defendant to each plaintiff for three quarterly reports to be selected by plaintiffs (said selection to be made in writing by **MARCH 31, 2010 AT NOON.**)

10. All communications and audits with or by CMS or IROs concerning the accuracy of AMPs and BPs in said reports.

11. All emails and memos that refer to "AMP" or "BP" sent or received by those assigned to help prepare or to review the reports to CMS (as well as, for emails, any other emails in the same chain).

All of the foregoing must be produced by **APRIL 30, 2010 at Noon.** If subpoenas to third parties are needed, plaintiffs must serve them promptly. On or before **June 18, 2010,** each defendant must make available one deponent who must be knowledgeable about the way in which the defendant calculated the AMP, BP, and URA for a one-day deposition. The deposition shall address the location and existence of further documents relevant thereto.

Each defendant may have until **MARCH 31, 2010, at Noon** to meet and confer with plaintiffs to refine or streamline the foregoing. If they reach an agreement in writing and signed by both sides then the substitutes shall apply. If not, the foregoing shall apply. In no event shall the deadlines be changed.

If any responsive material is withheld as privileged, then it must be described in a privilege log served by **APRIL 30, 2010, at Noon.** The privilege logs must be sufficiently detailed and informative to justify the privilege. No generalized claims of privilege or work-

product protection shall be permitted. With respect to each communication for which a claim of privilege or work product is made, the asserting party must at the time of its assertion identify: (a) all persons making and receiving the privileged or protected communication; (b) the steps taken to ensure the confidentiality of the communication including affirmation that no unauthorized persons have received the communication; (c) the date of the communication; and (d) the subject-matter of the communication. Failure to furnish this information at the time of the assertion will be deemed a waiver of the privilege or protection.

Based on the foregoing Stage One discovery, both sides shall then file proposals for Stage Two discovery. Each side may have up to 40 pages. All defendants must share the 40 pages. The purpose of the submissions shall be to frame the Stage Two discovery. The same memoranda shall describe any further discovery or proceeding appropriate under Rule 23. These memoranda must be filed simultaneously by **JUNE 28, 2010, at Noon**, and a hearing therein shall be held on **JULY 8, 2010, AT 11:00 A.M.**

As to BMS, the foregoing does *not* apply due to the extensive agency review already done. Counsel must meet and confer and agree on a substantially narrowed universe of materials to be produced, failing which no BMS materials need be produced without a further order. As to AstraZeneca and Bayer, their motions for special relief are **DENIED**. They must produce the same discovery as all other defendants (except BMS).

*Appendix C*

* * *

Finally, this must be said. Although the undersigned judge was originally unconvinced that these plaintiffs were ever intended to have third-party beneficiary rights under these federal contracts, defense counsel were unable to sustain that view on appeal. The appellate court also rejected the defense's primary jurisdiction argument. There have now been two trips to the court of appeals. Defendants have lost twice. The hour has come for the defendants to accept the verdict on appeal and to assist this Court in making the remand work and to litigate this case to a just, speedy, and inexpensive determination. Neither side should ask for extensions or reconsideration, but should roll up their sleeves and do the work needed.

**CONCLUSION**

The parties shall comply with all deadlines regarding the discovery stages listed above.

**IT IS SO ORDERED.**

## APPENDIX D — ORDER GRANTING MOTION FOR PROTECTIVE ORDER AND CERTIFYING INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. 1292(B) OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA DATED NOVEMBER 25, 2008

**UNITED STATES DISTRICT COURT**
**N.D. CALIFORNIA**

**No. C 05-03740 WHA.**

COUNTY OF SANTA CLARA, on behalf of itself and all others similarly situated,

Plaintiff,

v.

ASTRA USA, INC.; Astrazeneca Pharmaceuticals LP; Aventis Pharmaceuticals, Inc.; Bayer Corp.; Bristol-Myers Squibb Co.; Pfizer, Inc.; Schering-Plough Corp.; Smithkline Beecham Corp.; TAP Pharmaceutical Products, Inc.; Wyeth, Inc.; Wyeth Pharmaceuticals, Inc.; Zeneca, Inc.; ZLB Behring LLC; and Does 1 through 100, inclusive,

Defendants.

Nov. 25, 2008.

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## ORDER GRANTING MOTION FOR PROTECTIVE ORDER AND CERTIFYING INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. 1292(b)

WILLIAM ALSUP, District Judge.

### INTRODUCTION

In this proposed class action, the County of Santa Clara alleges that, through its public health service, it paid several drug manufacturers prices for drugs greater than price ceilings imposed by Section 340B of the Public Health Service Act of 1992 and contractual agreements thereunder. After an appeal and remand reinstating a contract claim as third-party beneficiary, defendants moved for a protective order limiting the subjects into which plaintiff may seek discovery, the motion based upon an express limitation in the appellate order. The motion requires resolution of important questions regarding the meaning of the pertinent contractual agreements and the permissive scope of this lawsuit going forward. For the reasons that follow, defendants' motion for a protective order is **GRANTED.** The order, however, is certified under 28 U.S.C. 1292(b) for immediate appeal for confirmation of this Court's interpretation of the following passage from the Ninth Circuit's recent order in this case:

> The PPA is drafted, for instance, so that covered entities are entitled only to the average manufacturer price reported to the Secretary; *they cannot claim that the reported figure was itself somehow erroneous.*

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*County of Santa Clara v. Astra USA, Inc.*, 540 F.3d 1094, 1109 (9th Cir.2008) (emphasis added). The essence of the problem is that plaintiff now wishes to go behind "the reported figure" and investigate whether the figure should have been reported lower. This order hews to the plain meaning of the Ninth Circuit ruling but this question will be certified.

## STATEMENT

Plaintiff, the County of Santa Clara, a public entity which owns and operates the Santa Clara Valley Health and Hospital System, alleges that defendants, several pharmaceutical manufacturers, breached contractual duties owed to plaintiff as a third-party beneficiary of agreements between defendants and the Secretary of the Department of Health and Human Services ("HHS") called Pharmaceutical Pricing Agreements ("PPAs"). The agreements implement statutory obligations that arise under Section 340B of the Public Health Service Act of 1992. 42 U.S.C. 256b. Congress passed Section 340B to provide discounts on outpatient drugs to qualified hospitals and clinics. That section, entitled "Limitation on prices of drugs purchased by covered entities," stated at all relevant times:

> The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average

> manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

*Id.* at 256b(a)(1) (bracketed text in original). The Secretary administered the program through the Health Resources and Services Administration ("HSRA"), an agency within HHS; more specifically, by HSRA's Office of Pharmacy Affairs.

Acting pursuant to Section 340B, the Secretary entered into Pharmaceutical Pricing Agreements with drug manufacturers, including defendants. Section II(a) of the PPA stated (Def. Req. Notice Exh. D at 5; emphasis added).[1]

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1. Pursuant to FRE 201, defendants' request that the Court take judicial notice of the HSRA's model PPA is granted (Def, Req. Notice Exh. D). The PPA is publicly available on HSRA's website. The parties make several additional requests for judicial notice. Plaintiff asks that the Court take judicial notice of three reports by HHS's Office of Inspector General (Pl. Req. Notice Exh. A-C). Pursuant to FRE 201, the Court takes judicial notice of the three reports. Defendants also request judicial notice of several documents (Def. Req. Notice Exh. A-P). The Court takes judicial notice of the PPA, the 2006 Office of the Inspector General report, and the agencies' guidance regarding the calculation of the AMP (Def. Req. Notice Exh. D, E-K). Defendants' remaining requests are moot as those documents are not pertinent to the issues decided in this motion.

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Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:

> (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug *that does not exceed an amount equal to the AMP for the covered outpatient drug reported* (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) *to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3)* of the Social Security Act, reduced by the rebate percentage.

In this lawsuit, plaintiff contends that defendants violated their obligations under the PPA to plaintiff, a third-party beneficiary of the agreements, by charging plaintiff a price exceeding the price ceiling defined in Section 340B and the PPA.

Section 340B and the PPA set the price limitation by reference to the *average manufacturer's price* ("AMP"), a term both the PPA and Section 340B defined by incorporating statutory definitions prescribed for a Medicaid drug rebate program. The Medicaid program was (and still is) administered by the Center for Medicaid Services ("CMS"), an agency within HHS. Although manufacturers rather than the agency calculated the AMP, the agency was permitted (but not required) to audit the manufacturers' reported AMP data. *Id.* at

§ 1396r8(b)(3)(B)-(C). The agency also provided manufacturers with guidance regarding how to calculate the AMP (Br. at 5-6; Def. Req. Not. F-K). Pursuant to intra-agency agreements, after being reported to CMS, the AMP and best-price data were provided to HSRA for use in the Section 340B program.

Plaintiff's contract claim alleges that defendants charged plaintiff a price greater than the price ceiling agreed upon in the PPA (and required by Section 340B). Plaintiff filed this lawsuit following a series of reports by HHS's Office of Inspector General ("OIG") raising concerns about overcharges. OIG issued a report in March 2003 that concluded that five manufacturers had overcharged various 340B-covered entities during a one-year period ending September 30, 1999. OIG issued another report in June 2004 that examined the prices paid by 340B entities in a sample month, September 2002, and again found overcharges. OIG, however, withdrew the June 2004 report, explaining that it had identified problems with the report's underlying data. The agency issued additional reports on Section 340B drug prices in 2005 and 2006.

Plaintiff filed in the Superior Court of Alameda County in August 2005, and the case was removed to federal court. After a first motion to dismiss was granted, defendants moved to dismiss all claims in the second amended complaint for failure to state a claim. The motion also asserted various defenses, including primary jurisdiction. A May 2006 order granted the motion (without reaching the primary jurisdiction argument).

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On appeal, the Ninth Circuit ruled that plaintiff *was* a third-party beneficiary of the Pharmaceutical Pricing Agreement and therefore may proceed with its contract claim. The decision also addressed defendants' alternate claim for dismissal based on primary jurisdiction. It ruled that the doctrine of primary jurisdiction did *not* require that the claim be stayed or dismissed without prejudice pending its referral to the Secretary for agency resolution. Its stated reason for rejecting primary jurisdiction is now the critical premise for this protective order motion:

> In our view, there is nothing "particularly complicated" about Santa Clara's contract claim on the merits. Santa Clara alleges that the Manufacturers did not comply with their obligation under the PPA to charge covered entities a price that "does not exceed . . . the [average manufacturer price] for the [covered drug] reported . . . to the Secretary in accordance with the Manufacturer's responsibilities under [§ 1396r-8(b)(3) ] . . . reduced by the rebate percentage." *See* PPA § II(a) (emphasis added). Contrary to the Manufacturers' suggestion, resolution of this claim presents no "far-reaching question that 'requires expertise or uniformity in administration.'" *Cf. Brown*, 277 F.3d at 1172. *The PPA is drafted, for instance, so that covered entities are entitled only to the average manufacturer price reported to the Secretary; they cannot claim that the reported*

> *figure was itself somehow erroneous.* Moreover, when a covered entity sues a manufacturer for failing to comply with its ceiling price obligations under the PPA, but "'does not seek to impose any additional or contrary obligations[,][it] is merely enforcing the existing rebate program responsibilities and does not inject any more variation than if the Department of Justice brought suit.'" *See generally Massachusetts v. Mylan Labs.*, 357 F.Supp.2d 314, 329 (D.Mass.2005) (quoting amicus brief of the United States filed in suit brought by states to enforce Medicaid State Rebate Agreement). We do not understand Santa Clara's complaint as taking issue with the agency's established guidance for calculating prices under § 1396r-8, so we conclude that its contract claim does not implicate DHHS's primary jurisdiction.

*County of Santa Clara v. Astra USA, Inc.*, 540 F.3d 1094, 1109 (9th Cir.2008) (emphasis added).

On remand, a case management conference was held in September 2008, at which the parties were instructed to proceed with discovery. As permitted at the conference, defendants subsequently brought the instant motion for a protective order to prevent discovery into the data and manner by which the "reported figures" were derived, *i.e.*, "the calculation of the Medicaid-derived components of 340B ceiling prices," the AMP and best-price data (Br. at 2).

Relying predominantly on the italicized sentence in the above-quoted primary jurisdiction holding, defendants argue that the only way the contract claim survived the primary jurisdiction defense was by the above limitation-namely, by limiting the contract claim to whether defendants honored the *reported* figure in its sales to the county—not whether errors occurred in the manufacturers' reporting of the data underlying that calculation. Evidently, this case is worth little unless plaintiff is allowed to go behind the reported numbers, for it appears from counsel's discussion at the hearing that there was substantial compliance, though not perfect compliance, with the reported numbers.

The Section 340B ceiling price (per unit) is calculated by the following simple formula:

*AMP-Unit Rebate Amount = Ceiling Price*

42 U.S.C. 256b(a)(1)-(2). The average manufacturer's price ("AMP") is (simplifying slightly) just the average price paid to the manufacturers by wholesalers in the United States. 42 U.S.C. 1396r-8(b)(3)(A), (k)(1). The unit rebate amount ("URA") is, in some circumstances, just a fixed percentage of the AMP, and in others is the AMP minus the "best price," term defined as (again simplifying slightly) the manufacturers' best price charged to wholesalers, with certain exclusions. 42 U.S.C. 1396r-8(c). Both the AMP and the "best price" are calculated or collected *by the manufacturers* and are then simply *reported to* the Secretary. *Id.* at § 1396r-8(b)(3)(A). Once that data are reported, the calculation

of the Section 340B ceiling price is a fairly simple, mechanical, arithmetic calculation.

The question presented by the motion is whether the manufacturers' contractual obligation to plaintiff, a third-party beneficiary of the agreement, is simply to charge a price no greater than the AMP minus URA calculated from the data *actually reported* to the Secretary (whether or not they were *accurately* reported), or rather is to charge a price no greater than the AMP minus URA calculated with AMP and best price figures that should have been reported. Defendants argue that plaintiff may not, through discovery, "look behind" the *reported* AMP or best price figures, to determine whether those figures were accurately reported according to the dictates of Section 340B, the agreement, and the Secretary's policy guidance. Rather, defendants argue, plaintiff is entitled only to the *actually reported* AMP and best price figures, to determine whether the ceiling prices were properly derived taking those as given.

The parties' positions on this question arise from differing interpretations of the contract-the PPA. Section II(a) of the PPA states (emphasis added):

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:
>
> (a) for single source and innovator multiple source drugs, to charge covered entities a

> price for each unit of the drug *that does not exceed an amount equal to the AMP for the covered outpatient drug reported . . . to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3)* of the Social Security Act, reduced by the rebate percentage.

Defendants rely predominantly on the sentence in the appellate order quoted above but repeated here for convenience:

> The PPA is drafted, for instance, so that covered entities are entitled only to the average manufacturer price reported to the Secretary; they cannot claim that the reported figure was itself somehow erroneous.

*County of Santa Clara*, 540 F.3d at 1109.

As stated, this is an important part of plaintiff's case. At the hearing, defendants indicated that, if the reported figures are taken as given, instances of overcharges will be isolated and *de minimus*. If true, plaintiff's only avenue for recovery on their claim for overcharges is to go behind the reported numbers to show that those reported numbers were too high.[2]

2. Defendants indicate that, even under their interpretation, some minimal issues would remain. For example, there has been some indication of isolated problems in the conversion from per-unit (*i.e.*, per-pill) to full-product or (Cont'd)

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For the reasons stated below, the undersigned would be inclined to permit the contested discovery but cannot in good faith do so given the language from the Ninth Circuit opinion that plaintiffs "cannot claim that the reported figure was itself somehow erroneous." The Ninth Circuit clearly stated that plaintiff cannot look behind the reported figures to demonstrate that those reported figures were incorrect. The quoted passage is a "show stopper."

## ANALYSIS

Were we writing on a clean slate, a plausible argument would favor allowing the discovery in question. The PPA obligates defendants as follows (Def. Req. Notice Exh. D at 5; emphasis added):

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:
>
> (a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed *an amount equal to the AMP for the covered outpatient drug reported* (or which would have been reported had the

(Cont'd)

container ceiling prices. Also, on occasion, the above-described formula can produce a negative ceiling price, and in such cases the Section 340B regime dictates a price of one cent. There have been indications of isolated problems applying that rule.

> Manufacturer participated in the Medicaid rebate program) *to the Secretary in accordance with the Manufacturer's* responsibilities under section 1927(b)(3) of the Social Security Act [, 42 U.S.C. 1396r-8(b)(3)], reduced by the rebate percentage.

The PPA does not merely instruct manufacturers to charge a ceiling price calculated from the AMP "reported"; it instructs manufacturers to use the AMP "reported . . . to the Secretary *in accordance with the Manufacturer's responsibilities under* [42 U.S.C. 1396r-8(b)(3) ]." As stated, Section 1396r-8(b)(3), in turn, requires manufacturers to report the AMP *as defined* in Section 1396r-8(k)(1). If manufacturers reported wrongly calculated AMPs, therefore, plaintiff has an argument that the manufacturers failed to live up to their obligation under the PPA.

The parties dispute the meaning of the phrase "*in accordance with* the Manufacturer's responsibilities under [the Act]." That language must be interpreted in context. *County of Santa Clara*, 540 F.3d at 1102 (courts must weigh the circumstances of the transaction, including here, the governing statute and its purpose). Section II of the PPA states that the obligations therein arise "[p]ursuant to requirements under section 340B of the Act." Section 340B, in turn, states:

> [t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid

> . . . *does not exceed* an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 U.S.C.A. § 1396 et seq.] . . . reduced by the rebate percentage described in paragraph (2).

42 U.S.C. 256b(a)(1) (emphasis added). Section 340B prescribes not merely a ceiling price calculated from "reported" figures, but instead that manufacturers enter agreements under which the prices paid for drugs "do[ ] not exceed" the statutorily defined price ceiling. It is unlikely, therefore, that the disputed "in accordance with" language merely "directs a reader to the particular manufacturer [AMP] reports at issue," as defendants have argued. Rather, the PPA implements Section 340B's substantive pricing obligation. The Ninth Circuit interpreted the PPA in this manner:

> In acceding to the PPA, the Manufacturers undertook a specific responsibility to the covered entities: "Pursuant to [§ 256b], the Manufacturer agrees . . . . to charge covered entities a price for each unit of the drug that does not exceed" the ceiling price of that drug . . . . *Section II(a) of the PPA sets forth an unambiguous, concrete limitation on how much the Manufacturers may charge* the covered entities . . . . Upon a fair reading of the PPA, we are unable to discern any substantial purpose of the PPA other than to grant eligible covered entities a discount on covered drugs.

*Id.* at 1102-03 (emphasis added).

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Plaintiff's complaint specifically averred that "[t]he data necessary to identify the overpayments for § 340B drugs is under the exclusive control of defendants, including, but not limited to, *the data underlying the AMP*, the best price and the § 340B ceiling price calculations. Indeed, the OIG confirmed that participating entities cannot verify that they receive the § 340B ceiling price due to confidentiality provisions in the authorizing statute" (Compl. ¶ 45; emphasis added). The Ninth Circuit's decision arguably contemplated the discovery of such otherwise-confidential pricing information:

> the confidentiality provision anticipates that disclosures could be required other than to or by the Secretary. A district court's discovery order compelling the production of documents would be a disclosure 'required by law'; and it would be the manufacturer, not the Secretary, disclosing the information.

*County of Santa Clara*, 540 F.3d at 1105-06. The appellate decision ruled that plaintiff's contract claim can proceed; it did not state, at least not in so many words, that such discovery would be limited to the AMP data which the manufacturers had already reported to the agency. Similarly, the Ninth Circuit decision quoted a District of Massachusetts decision with approval. *Massachusetts v. Mylan Labs.*, 357 F.Supp.2d 314, 329 (D.Mass.2005). That decision—which addressed the Medicaid program rather than the Section 340B

program—contemplated an inquiry into the accuracy of the reported figures such as the "best price" data. *Ibid.*[3]

Defendants argue that allowing plaintiff the contested discovery would be akin to allowing the "tail to wag the dog" because, if permitted to question the accuracy of the reported figures, the claim could have ramifications not only for the Section 340B program but also for the much larger Medicaid rebate program from which Section 340B draws the AMP and best price data (Br. at 13, 16-17; Reply at 3). The undersigned finds this argument unpersuasive. If defendants have *not* committed significant reporting errors, there should be no widespread impact on the Medicaid rebate program, and if defendants *have* systematically misreported data to the Medicaid program, defendants fail to explain why it would be undesirable (for anyone other than defendants) for such conduct to come to light. In fact, under defendants' interpretation of the PPA, even if reporting problems were to be discovered in the ongoing litigation concerning the Medicaid program, *see Massachusetts v. Mylan Labs.*, 357 F.Supp.2d 314 (D.Mass.2005), covered entities under the *Section 340B* program such as plaintiff would have no recourse because defendants' duties under the PPA and Section 340B would be limited to charging ceiling prices

3. The Ninth Circuit emphasized the similarities between the rights of third-party beneficiaries under the two programs: "[t]he relationship between states and manufacturers under the Medicaid State Rebate Agreement is roughly analogous to that between covered entities and manufacturers under the PPA." *County of Santa Clara*, 540 F.3d at 1109 n. 21.

calculated from the figures that had *actually been reported* under the Medicaid program, even if those reported figures were inaccurate.

For these reasons, given the contract ruling by the appellate court, the undersigned would be somewhat inclined to interpret the PPA as creating a duty to charge ceiling prices calculated with *accurately reported* AMP and best price figures, not merely a ceiling price calculated from *as-reported* figures.

The slate, however, is not clean. The undersigned is unable to overlook the following clear-cut statement of the Ninth Circuit's decision, a statement that seems to have been central to its primary jurisdiction holding:

> [t]he PPA is drafted, for instance, so that covered entities are entitled only to the average manufacturer price reported to the Secretary; they cannot claim that the reported figure was itself somehow erroneous.

That is precisely what plaintiff seeks to do-plaintiff claims that the *reported figures* were somehow erroneous and seeks discovery to go behind the reported figures. The Court has considered the possibility that, because the italicized passage referred to the "average manufacturer price," the appellate court intended its limitation to apply only to that "reported figure" and did not intend any limitation as to the "best price." Since, however, the "best price" is also an allied "reported figure," there is no reasoned way to draw such

a limitation. The rationale of the appellate court, as reflected in the italicized passage, appears to be a limitation on both reported figures.

Defendants' motion for a protective order is therefore granted, and the question is certified for immediate appeal under Section 1292(b).

## CONCLUSION

For all of the above-stated reasons, defendant's motion for a protective order is **GRANTED.** This order is certified for immediate appeal under 28 U.S.C. 1292(b). The undersigned finds that the above-described question involves "a controlling question of law as to which there is substantial ground for difference of opinion" and that "an immediate appeal from the order may materially advance the ultimate termination of the litigation." Discovery will meanwhile proceed on all other issues.

**IT IS SO ORDERED.**

## APPENDIX E — ORDER DISMISSING SECOND AMENDED COMPLAINT OF THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA DATED MAY 17, 2006

**UNITED STATES DISTRICT COURT**
**N.D. CALIFORNIA**

**No. C 05-03740 WHA.**

COUNTY OF SANTA CLARA, on behalf of itself and all others similarly situated,

Plaintiff,

v.

ASTRA USA, INC.; Astrazeneca Pharmaceuticals Lp; Aventis Pharmaceuticals, Inc.; Bayer Corp.; Bristol-Myers Squibb Co.; Pfizer, Inc.; Schering-Plough Corp.; Smithkline Beecham Corp.; Tap Pharmaceutical Products, Inc.; Wyeth, Inc.; Wyeth Pharmaceuticals, Inc.; Zeneca, Inc.; Zlb Behring Llc; and Does 1 through 100, inclusive,

Defendants.

May 17, 2006.

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## ORDER DISMISSING SECOND AMENDED COMPLAINT

WILLIAM ALSUP, District Judge.

## INTRODUCTION

In this action alleging overpricing of medicine, defendants move to dismiss the second amended complaint. The motion is **GRANTED.**

## STATEMENT

The Public Health Service Act of 1992 established a drug discount program called the Section 340B program. 42 U.S.C. 256b. The 340B program requires participating pharmaceutical manufacturers to provide statutorily defined discounts on outpatient drugs to qualified hospitals and clinics. Manufacturers are required to participate in the 340B program as a condition of having drug charges reimbursed by Medicaid. Manufacturers working through Medicaid must enter into a Pharmaceutical Pricing Agreement with the Secretary of the Department of Health and Human Services. That agreement limits the prices drug makers may charge. The 340B program is overseen by the Health Resources and Services Administration ("HRSA"), an agency within the department. Immediate responsibility for oversight of the 340B program resides in HRSA's Office of Pharmacy Affairs.

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This lawsuit was evidently provoked by a series of federal reports raising concerns about overcharges. In March 2003, the Office of Inspector General of the Department of Health and Human Services issued a report entitled "Pharmaceutical Manufacturers Overcharged 340B-Covered Entities." The report stated that five pharmaceutical manufacturers had overcharged various 340B entities during the one-year period ending September 30, 1999. The OIG issued another report in June 2004 entitled "Appropriateness of 340B Drug Prices." It examined the prices paid by various 340B entities in September 2002. It found that 340B entities overpaid and did not receive the correct discount for thirty-one percent of sampled drug purchases. The report estimated that 340B entities overpaid $41.1 million for the sample month. No specific manufacturers, 340B entities or drug prices were identified in the report. On October 21, 2004, the OIG withdrew the June 2004 report after finding problems with data used to conclude that entities were overcharged. The OIG expects to release a new report to determine whether 340B entities paid the appropriate price.

Santa Clara County sued defendants in Alameda County Superior Court, claiming they had overcharged for drugs. After removal to federal court, a motion for remand was denied. Plaintiff's first amended complaint was dismissed entirely with leave to amend. The second amended complaint is the target of the instant motion. It reiterates claims in the first amended complaint, namely violations of California's Unfair Competition Law

and False Claims Act and for an accounting. It adds claims for breach of contract, for breach of the covenant of good faith and fair dealing, for negligence and in quantum meruit.

## ANALYSIS[1]

A motion to dismiss under Rule 12(b)(6) tests the legal sufficiency of the claims alleged in the complaint. A complaint should not be dismissed "unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957). On the other hand, "conclusory allegations of law and unwarranted inferences are insufficient to defeat a motion to dismiss for failure to state a claim." *Epstein v. Wash. Energy Co.*, 83 F.3d 1136, 1140 (9th Cir.1996).

"[T]he Federal Rules of Civil Procedure do not require a claimant to set out in detail the facts upon which he bases his claim. To the contrary, all the Rules require is 'a short and plain statement of the claim' that will give the defendant fair notice of what the plaintiff's claim is and the grounds upon which it rests." *Conley*, 355 U.S. at 47 (quoting Rule 8(a)(2)). Allegations of fraud, however, must meet the heightened pleading standards of FRCP 9(b). These require allegations of particular facts going to the circumstances of the fraud, including

1. This order addresses only the motions to dismiss brought by all defendants. Two other motions to dismiss are either moot or were withdrawn.

time, place, persons, statements made and an explanation of how or why such statements are false or misleading. *In re Glenfed, Inc. Sec. Litig.*, 42 F.3d 1541, 1547-48 n. 7 (9th Cir.1994) (en banc).

**1. JUDICIAL NOTICE.**

Defendants ask for judicial notice of various government and court documents, an annual report of GlaxoSmithKline plc and news articles from *The Wall Street Journal* and the Associated Press. Plaintiff do not oppose the requests. Judicial notice is proper when the matter of which notice is taken is "capable of accurate and ready determination by resort to sources whose accuracy cannot reasonably be questioned." FRE 201(b), (b)(2). The materials of which defendants ask the Court to take notice meet these criteria. The Court therefore takes judicial notice of the existence and contents of all the materials listed in the requests.

**2. UNFAIR COMPETITION CLAIM.**

The claim in the first amended complaint for violation of California Business and Professions Code 17200, the Unfair Competition Law, was dismissed because counties do not have standing to bring such actions in the circumstances of the instant action. Santa Clara argues that its new UCL claim nevertheless must be sustained because it "includes additional named plaintiffs, namely, the Section 340B entities . . ." (Opp.8).

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The body of the second amended complaint includes a paragraph with the headings "Parties," and then "Plaintiffs." It identifies the plaintiffs as follows (Second Am. Compl. (hereinafter "Compl.") ¶ 10):

Plaintiffs include the County of Santa Clara, a public entity which owns, operates and provides health services by and through the Santa Clara Valley Health and Hospital System ("SCVHHS"), and its various clinics and subdivisions, including the following: Santa Clara Valley Medical Center ("SCVMC"), Surgical Daycare 5 West, Electro Encephalography, Oncology Clinic, Moorpark Clinic Pharmacy, Silver Creek Clinic Pharmacy, Out Patient Clinic Pharmacy, East Valley Clinic Pharmacy, South Valley Clinic Pharmacy, Valley Health Center Clinic Pharmacy, Chronic Peritoneal Dialysis-Home, Renal Dialysis, Emergency Department, East Valley Clinic, South Valley Clinic, Silver Creek Clinic, Valley Health Center Administration, MPC Primary Care, Valley Health Center Cardiology Clinic, MPC Diabetes and Metabolism Center, Valley Health Center Dermatology/Allergy, Mobile Medical Services, Valley Health Center Pediatrics, Valley Health Center Rheumatology, Valley Health Center Bascom Urgent Care, Valley Health Center OB/GYN, MPC Employee Health/Occupational Medicine, Tully Clinic, OPD-Urgent Care Clinic, Pep Lab, Fair Oaks Community Clinic, Nephrology Clinic, OPD ENT & Eye, OPD Medical Speciality, OPD Surgery, Chaboya Dental Services, OPD Ortho Clinic, MPC Rehab Clinic,

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Tully Clinic Pharmacy, Homeless Healthcare, In-Service Education-Nursing, Office of Disaster Medical Supplies . . . .[2]

This description is ambiguous. To clear it up, the Court asked for clarifying declarations from each entity named in paragraph ten. Instead of unequivocally saying whether they had brought suit as parties separate from the county, each entity responded by submitting identically cagey statements through the same county health official.

The complaint could be read as stating that the plaintiff is the "County . . . which provides health services . . . through the Santa Clara Valley Health and Hospital System[ ] and its various clinics and subdivisions." That reading views this as a single-plaintiff complaint. The description alternatively could be interpreted to state that the "Plaintiffs . . . [are] the County . . . and its various clinics and subdivisions." That construction contemplates multiple plaintiffs.

This much seems clear: the health-care providers all are owned and operated by the county (Compl.¶ 10). The Santa Clara Valley Health and Hospital System is

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2. The caption of the complaint identifies only the county as plaintiff. The caption, however, is only "the handle to identify" the lawsuit. The identity of defendants normally is determined by reference to "the allegations in the body of the complaint and not upon [their] inclusion in the caption." *Hoffman v. Halden*, 268 F.2d 280 303-04 (9th Cir.1959). There is no reason not to extend this rule to govern the identity of plaintiffs.

merely an agency of the county. The Medical Center is, in turn, a department within the Hospital System. The Medical Center and the Hospital System are controlled by the county executive, who in turn is appointed and can be removed by the county board of supervisors. County of Santa Clara, Cal., Code §§ A18-1, A18-33 (2005); County Charter § 301(c).

Furthermore, the Medical Center and Hospital System are not authorized by state law to bring civil actions. County ordinances also prevent them from taking legal action on their own. The legal officer for the Medical Center and the Hospital System is the county counsel; they may not employ or consult with any outside attorney unless the county counsel agrees. County Code § A22-16. The county counsel, in turn, is chosen and can be removed by the county board of supervisors. County Charter § 301(c). In short, the Medical Center, Hospital System and apparently all the health providers named in paragraph ten of the complaint are mere alter egos of the county without the capacity to bring suit on their own.

At the hearing, plaintiff's counsel acknowledged the basics of the relationship between the county and the medical groups named in the complaint. He stated that the Hospital System was a county agency, the plaintiff entities were subunits of it, that the Hospital System cannot sue on its own and that it will be bound by any judgment in this action.

As held in the earlier order, counties cannot sue for violations of Section 17200 in this type of case. Entities controlled and owned by the county that have no capacity to sue on their own therefore also cannot bring Section 17200 claims. Allowing them to do so would merely permit counties to do by subterfuge what they are barred from doing directly. For this reason, none of the possible plaintiff entities have standing to maintain the UCL claim.

**3. FALSE CLAIMS ACT CLAIM.**

"California's False Claims Act . . . is patterned largely on [the federal False Claims Act]." *California ex rel. Bowen v. Bank of Am. Corp.*, 126 Cal.App. 4th 225, 236 (Cal.Ct.App.2005). "Complaints brought under the [federal False Claims Act] must fulfill the requirements of Rule 9(b). . . ." *Bly-Magee v. California*, 236 F.3d 1014, 1018 (9th Cir.2001). Absent exceptional circumstances, therefore, a claim under the California False Claims Act will be treated as one for fraud and must satisfy the pleading standards of FRCP 9(b) when brought in federal court. Plaintiff here explicitly alleges that "[d]efendants *fraudulently* concealed and failed to disclose the facts that they charged plaintiffs more than the best price" (Compl.¶ 54) (emphasis added). Plaintiff does not concede directly that its False Claims Act allegations sound in fraud but it tacitly accepts defendants' contention that it must satisfy the heightened pleading requirements. Furthermore, plaintiff does not allege any facts to suggest that defendants submitted false claims unwittingly or

negligently. For these reasons, plaintiff's False Claims Act allegations must meet the requirements of FRCP 9(b).

FRCP 9(b) requires that "[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity."

> Rule 9(b) serves not only to give notice to defendants of the specific fraudulent conduct against which they must defend, but also to deter the filing of complaints as a pretext for the discovery of unknown wrongs, to protect [defendants] from the harm that comes from being subject to fraud charges, and to prohibit plaintiffs from unilaterally imposing upon the court, the parties and society enormous social and economic costs absent some factual basis.

*Bly-Magee*, 236 F.3d at 1018 (citation omitted).

"Rule 9(b) may be relaxed to permit discovery in a limited class of corporate fraud cases where the evidence of fraud is within a defendant's exclusive possession." *United States ex rel. Lee v. SmithKline Beecham, Inc.*, 245 F.3d 1048, 1052 (9th Cir.2001). "In such cases, the particularity requirement may be satisfied if the allegations are accompanied by a statement of the facts upon which the belief is founded." *Wool v. Tandem Computers Inc.*, 818 F.2d 1433, 1439 (9th Cir.1987) (citation omitted).

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Although drug manufacturers are required to provide their pricing information to the Department of Health and Human Services, confidentiality provisions prevent the Secretary from disclosing this pricing information. 42 U.S.C. 1396r-8(b)(3)(D). To be sure, there is a process to obtain *certain* pricing information. The OIG's October 2005 report discussed a survey of 340B entities and the process of obtaining pricing information.

Entities may submit written requests to HRSA for 340B price approximations, but survey respondents viewed this process as cumbersome and inefficient. HRSA staff confirmed that they are only able to review price requests limited to 10 products at a time due to staffing limitations. Further, due to the confidentiality provisions, HRSA can only provide a general indication to the entity on whether the price is over the ceiling. In other words, if an entity's reported price exceeds the ceiling price, HRSA can inform the entity of the overcharge, but not the extent of the overcharge.

OIG, Dep't of Health & Human Services, No. OEI-05-02-00072, Deficiencies in the Oversight of the 340B Drug Pricing Program at 18 (2005).

The information obtained through this process is of limited value. *First,* the price requests are limited to ten products at a time. Here, plaintiff's list of purchased drugs is well in excess of ten different drugs. *Second,* plaintiff would not know the extent, if any, of overcharges. *Third,* plaintiff has reason to question the

validity of the data that underlies HRSA's price calculations. For example, the OIG's October 2005 report found "systematic problems with the accuracy and reliability of the Government's record of 340B ceiling prices." Therefore, this order rejects the notion that this avenue allowed plaintiff to gather facts of the particularity normally required under Rule 9(b).

Nonetheless, the question remains whether plaintiff's "allegations are accompanied by a statement of the facts upon which the belief is founded." *Wool*, 818 F.2d at 1439. It is upon this issue that the claim founders. Plaintiff has not submitted any actual invoices, although the second amended complaint lists the names, quantities and prices of drugs purchased during a sample three-month period. The list identifies the vendor, but does not indicate which 340B entity purchased the drugs.

As the Ninth Circuit has explained:

> The time, place, and content of an alleged misrepresentation may identify the statement . . . complained of, but these circumstances do not 'constitute' fraud. The statement in question must be false to be fraudulent. Accordingly, our cases have consistently required that the circumstances constituting falseness be set forth.

*In re Glenfed*, 42 F.3d at 1548.

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Plaintiff points to five items upon which it founds its belief that the claims are false. These five items are: (1) OIG's March 2003 report, "Pharmaceutical Manufacturers Overcharged 340B-Covered Entities"; (2) OIG's June 2004 report, "Appropriateness of 340B Drug Prices"; (3) OIG's October 2005 report, "Deficiencies in the Oversight of the 340B Drug Pricing Program"; (4) a letter from the chairman of the Senate Finance Committee to HRSA; and (5) allegations that certain defendants entered into three agreements to settle claims that they violated the Medicaid Drug Rebate statute.

None of the items provides a reasonable basis for inferring that any *particular* defendant engaged in the fraud alleged here. The OIG's March 2003 report examined sales from five manufacturers for eleven prescription drugs. The report estimated that the five manufacturers overcharged 340B entities $6.1 million for sales occurring during the one-year period ending September 30, 1999. Plaintiff states that defendants Aventis, Bristol-Myers, SmithKline Beecham and TAP were the manufacturers in the March 2003 report. The report did not identify the manufacturers, the eleven prescription drugs or the 340B entities. It is unclear what basis plaintiff has for asserting that those particular companies were the overcharging manufacturers. Moreover, plaintiff did not join the 340B program until 2001, *after* the period for which the OIG based its 2003 report. The June 2004 report examined the prices charged to 37 health-care providers. The report concluded that 36 of them did not receive the correct

discount on a third of their sampled drug purchases in September 2002. Again, no manufacturer, drug or 340B entity was identified. Significantly, the OIG withdrew the 2004 report that October. The OIG cited problems with the data it used to calculate the ceiling price. The October 2005 report did not address the issue of any overcharges to 340B entities. Instead, it examined HRSA's ability to ensure that 340B entities paid at or below the statutorily established ceiling price. The Senate Finance Committee's letter to HRSA added no new specific facts. The letter requested a status report on HRSA's progress in improving the 340B program.

Finally, plaintiff points to the outcomes of the Medicaid Drug Rebate actions taken against certain defendants for "best price" violations with respect to Medicaid. Plaintiff claims that these outcomes indicate an admission to overcharging for drugs. Plaintiff states that (Opp.5-6):

> [AstraZeneca] pled guilty and agreed to pay $355 million in fines for violating the best price requirements with respect to the sale of Zoladex; [Pfizer] agreed to pay $9 million to settle allegations that it violated the Medicaid Rebate Program; and [TAP] agreed to pay $875 million in fines, of which $559,483,560 was attributed to violation of best price reporting. [T]he County of Santa Clara and the 340B hospitals and clinics purchased drugs from these defendants and were therefore overcharged in violation of Section 340B.

*Appendix E*

The second amended complaint also notes that with respect to the Medicaid Drug Rebate Statute, "Schering-Plough did not report . . . . the best price as required" (Compl.¶ 66). To be sure, there is a link between the "best price" as used in determining the Medicaid rebate amount and the 340B ceiling price. Consequently, any error in "best price" reporting potentially could lead to an increase in prices charged to 340B entities.

There are three problems with plaintiff's argument. *First*, the complaint does not make clear the manner in which the Medicaid "best price" reporting was improper. Untimely reporting of the "best price" is one way of violating the rules without actually reporting false figures. 42 U.S.C. 1396r-8(b)(3)(C). *Second*, it is unclear whether these Medicaid actions involved events which were within the statutory limitations period of the complaint. *Third*, Santa Clara did not begin participation in the 340B program until 2001. Office of Pharmacy Affairs, Covered Entity database, *at* http://opanet.hrsa.gov/opa/CE/CEExtract.aspx (last viewed May 10, 2006). The complaint does not allege on what dates the "best price" reporting violations occurred. They could have occurred before plaintiff joined the 340B program. *Fourth*, these Medicaid violations cannot be imputed to all defendants.

The decisions cited by plaintiff are distinguishable from the facts of this action. In *Celador International Ltd. v. The Walt Disney Co.*, 347 F.Supp.2d 846, 855-56 (C.D.Cal.2004), the court found that under a relaxed

pleading standard the plaintiffs sufficiently stated a basis for their allegations. The plaintiffs specifically identified each defendant and identified its specific role in the alleged fraud. Here, plaintiff's statement of facts is based largely on government reports that never identified the manufacturer, drug or 340B entity. Additionally, one report was withdrawn while the other examined sales prior to plaintiff's entry into the 340B program.

Plaintiff cites *Deutsch v. Flannery*, 823 F.2d 1361 (9th Cir.1987). The plaintiff in *Deutsch* claimed that directors of a company schemed to depress the valuation of their company. In return, they were promised management positions in a new company. The complaint alleged fraud regarding a tender-offer document given by the directors to the shareholders. The plaintiff claimed that the document purposely failed to disclose the company's true value. The allegations included one that the company sold land carried on its books at $270,000 for $9,397,000. Another claimed that the company could have paid dividends but did not, as a way to suppress its market value. The facts pleaded in *Deutsch* were more specific than those here. There, the "defendants received precise statements of what they allegedly failed to disclose." *Id.* at 1366.

Plaintiff also cites *Wool*, 818 F.2d 1433. After finding that a relaxed FRCP 9(b) standard was warranted, *Wool* held that:

> [T]he paragraphs alleging misleading statements, misrepresentations, and specific

> acts of fraud are very precise. Each alleged misstatement is identified by content, date, and the document or announcement in which it appeared. The complaint specified the exact dollar amount of each alleged overstatement, and the manner in which such representations were false and misleading.

*Id.* at 1439-40.

Not so here. The complaint presents vague allegations that do not specify the content or date of alleged misstatements, the document in which they appeared or the amount of the overcharge. The False Claims Act allegations therefore are dismissed for failure to comply with FRCP 9(b).

**4. CONTRACT AND COVENANT-OF-GOOD-FAITH CLAIMS.**

Plaintiff claims that it has contract rights as a third-party beneficiary of the Pharmaceutical Pricing Agreements. It alleges that these agreements exist between the Secretary and all manufacturer defendants individually. Plaintiff claims that it was damaged by defendants' breach of the Agreements (Compl.¶¶ 102-104). Defendants seek dismissal on the ground that plaintiff is not a third-party beneficiary (Br.9-10).

The Agreements require that they be construed under federal common law (Agreement § VII(g)). Under federal law, an entity may sue on a contract to which it

is not a party if (1) the signatories intended it to benefit directly, *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303, 307-08 (1927), and (2) intended it to have the right to sue for performance.

> The intended beneficiary need not be specifically or individually identified in the contract, but must fall within a class clearly intended by the parties to benefit from the contract. . . . Parties that benefit from a government contract are generally assumed to be incidental beneficiaries, and may not enforce the contract absent a *clear intent* to the contrary.

*Klamath Water Users Protective Ass'n v. Patterson*, 204 F.3d 1206, 1211 (9th Cir.1999) (internal quotations and citations omitted) (emphasis added).

In addition to *Klamath*, there are two other main Ninth Circuit decisions governing third-party benefits under federal contracts. In each, the court emphasized that it would not grant third-party standing absent a "clear intent" to grant it. *Orff v.. United States*, 358 F.3d 1137, 1145, 1147, n. 5 (9th Cir.2004); *Smith v. Cent. Ariz. Water Conservation Dist.*, 418 F.3d 1028, 1035-38 (9th Cir.2005). In a fourth decision, there is no mention of the "clear intent" requirement. *Tyler v. Cuomo*, 236 F.3d 1124 (9th Cir.2000). In *Tyler*, the court held that homeowners who opposed a low-income housing project in San Francisco had third-party beneficiary status under a contract between the city and the Department

of Housing and Urban Development. The contract provided that if a "member of the public" makes a written complaint, "the City shall take the objection into account and consult as needed with the objecting party." The court held that this provision was enough to allow the homeowners' contract claim to go forward. *Id.* at 1134-35. In none of the four decisions did the Ninth Circuit go beyond the four corners of the contract to find the parties' intent.

We must decide whether to apply the "clear intent" requirement to the instant motion. It would be an easier decision if any of the four decisions turned on contractual provisions similar or identical to those in the Agreement. But they did not. It is significant, however, that three of the four decisions required clear intent. Although the fourth decision did not demand it openly, neither did it disavow the requirement. It simply was not mentioned. Given the weight of authority, this order applies the "clear intent" requirement.

In each Pharmaceutical Pricing Agreement, the manufacturer agreed "to charge covered entities a [discounted] price. . . ." The contract provided that the Secretary "may require the Manufacturer to reimburse the [covered] entity for discounts withheld" and requires the manufacturer to "hold audit information obtained from the covered entities confidential" (Agreement §§ II(a) IV(c), V(b)). These provisions clearly benefitted covered entities. Whether they reflected a clear intent to confer actionable rights is another matter.

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The Pharmaceutical Pricing Agreements assign the role of requiring reimbursements to the Secretary. To analyze this, we borrow the statutory-construction canon *"expressio unius est exclusio alterius"* ("the inclusion of one thing suggests the exclusion of all others"). *Barnhart v. Peabody Coal Co.*, 537 U .S. 149, 168 (2003) (describing canon). This canon suggests that when the parties gave this power to the Secretary, they intended to deny it to all others. That interpretation makes sense. If all of the more than 12,000 covered entities had standing to enforce the price controls, manufacturers would be subject to a crushing number of lawsuits, all arising out of the same contract. *See* Office of Pharmacy Affairs, Statistical Reports, Growth of 340B Covered Entity Sites *at* http://opanet.h rsa.gov/opa/Report/StatisticalReport.aspx (number of entities). It strains credulity to suggest that the manufacturers agreed to face such a threat. *See Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir.1987) (barring third-party standing to applicants for housing subsidies due to their multiplicity).[3]

Other courts of appeals have assessed intent by looking to background statutes, legislative history and implementing regulations. *See, e.g., Holbrook v. Pitt*, 643 F.2d 1261, 1271 (7th Cir.1981); *Audio Odyssey, Ltd. v. United States*, 255 F.3d 512, 521 (8th Cir.2001) (background legislation only). Those sources reinforce

3. In 1998, there were 7,000 340B entities. Growth of 340B Covered Entity Sites *at* http://opanet.hrsa.gov/opa/Report/StatisticalReport.aspx. This is still a huge number of potential parties to a contract lawsuit.

the conclusion that 340Bs are not third-party beneficiaries.

The legislative history of 42 U.S.C. 256b shows that its "purpose . . . is to enable . . . certain Federally-funded clinics to obtain lower prices" in the wake of a 32 percent rise in hospitals' drug costs. In recommending passage, the House Committee on Energy and Commerce intended "to enable [covered] entities to stretch scarce Federal resources as far as possible. . . ." Committee on Energy and Commerce, H.R.Rep. No. 102-384(II) at 7, 10-12 (1992). The Committee's emphasis on aiding covered entities suggests that Congress intended to benefit them directly. It does not, however, make clear that Congress wanted to confer upon them new rights to sue.

Administrative guidelines approved pursuant to 42 U.S.C. 256b provide a voluntary, informal process to resolve disputes between manufacturers and health-care providers. It includes an appeals phase. If the process finds that a manufacturer has overcharged an entity, "the manufacturer's agreement with [the Secretary] could be terminated or other actions taken. . . ." Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed.Reg. 65,406, 65,412-13 (Dec. 12, 1996). The availability of an administrative remedy to a particular person may be proof that the government did not intend that person to have rights under the contract:

> [A regulatory emphasis on] conciliation and informal resolution of complaints suggests

> strongly that [Congress] did not intend a conflicting private remedy . . . to be available. To conclude otherwise would mean Congress had purposefully established an elaborate administrative procedure whose effectiveness Congress intended to be undermined willy-nilly through the institution of private lawsuits.

*D'Amato v. Wis. Gas Co.*, 760 F.2d 1474, 1481-82 (7th Cir.1985). Although the 340B dispute-resolution process may not be "elaborate," its existence nevertheless suggests that health-care providers should not be able to bring claims under the Agreements.

Plaintiff relies on the Restatement's assertion that "[i]n some cases an overriding policy, which may be embodied in a statute, requires recognition of such a right without regard to the intention of the parties." Restatement § 302, cmt. d. *First*, an overriding policy is not enough in light of Ninth Circuit law requiring a "clear intent" in the contract. *Second*, plaintiff is not the only party situated to enforce the contract, nor is this action its only means to do so. The government may bring suit. It or plaintiff can engage in the dispute-resolution process. These facts weaken the value of a policy recognizing contract rights here. *Third*, comment d of Section 302 is trumped by Section 313 of the Restatement, which rejects third-party rights on government contracts whenever it would "contravene the policy of the law . . . prescribing remedies for [ ] breach." The policy of the law here is to remedy breaches via government action or the dispute-resolution process.

The above considerations militate against third-party beneficiary status to 340B entities and to plaintiff. Such rights might effectuate certain goals of the statute. There is not, however, the "clear intent" required to confer such rights. This claim cannot to go forward.

Rejection of the contract claim also ends the allegation of breach of an implied covenant of good faith and fair dealing (*see* Compl. ¶¶ 106-108). Neither the Ninth Circuit nor the Supreme Court has ever explicitly recognized that every contract formed under federal common law includes such a covenant. *Cf. Flores v. Am. Seafoods Co.*, 335 F.3d 904, 913 (9th Cir.2003) ("[U]nder federal contract law, at least in the context of admiralty law governing a seaman's rights and remedies, each contract carries with it a duty of each party to act in good faith and to deal fairly. . . ."). If such a covenant exists, however, it must be interpreted "by reference to traditional common law principles," *Minidoka Irrigation Dist. v. Dep't of Interior*, 154 F.3d 924, 926 (9th Cir.1998). In California, the covenant cannot form an independent basis of liability except under certain limited circumstances not present here. *Guz v. Bechtel Nat'l Inc.*, 24 Cal.4th 317, 352 (2000) ("To the extent the implied covenant claim seeks simply to invoke terms to which the parties did agree, it is superfluous). This order applies that rule to the federal contract at issue here. Plaintiff's covenant-of-good-faith-and-fair-dealing claim cannot exist independent of the contract claim. The contract claim is out. With it goes the covenant claim.

## 5. NEGLIGENCE.

Plaintiff alleges that defendants had a duty under tort law to "use due care to ensure that they did not charge plaintiffs prices above and beyond the § 340B ceiling prices mandated by law for the sale of outpatient drugs and products to § 340B entities" (Compl.¶ 97). Defendants seek dismissal of this claim on the ground that it had no such duty under tort law (Br.12-13).

Negligence in California is actionable pursuant to the Civil Code which provides that "[e]veryone is responsible . . . for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person," Cal. Civ.Code § 1714(a). *Rowland v. Christian*, 69 Cal.2d 108, 111-13 (1968). To allege negligence properly, the plaintiff must claim that the defendant was under a legal duty to use due care. *Toomey v. S. Pac. R.R.*, 86 Cal. 374, 381 (1890).

Plaintiff claims that the duty to use due care to ensure proper drug prices arose from three sources: legislation creating the 340B program, the Agreements and a "special relationship" between defendants and 340B entities (Opp.13-14).

The 340B statute did not create a duty for drug makers. The statute requires nothing of them. It requires the Secretary to "enter into an agreement with each manufacturer of covered drugs. . . ." The statute does not obligate the manufacturer to enter into that

agreement. The manufacturer must charge the lower prices only if it executes the agreement and sells to a 340B entity. 42 U.S.C. 256b(a)(1).

Plaintiff also cannot bootstrap breach of contract into a tort. "[C]onduct amounting to a breach of contract becomes tortious only when it also violates a duty independent of the contract arising from the principles of tort law." *Erlich v. Menezes*, 21 Cal.4th 543, 551 (1999) (internal quotation marks omitted). In this case, there is no allegation of an omission of a legal duty. Plaintiff's only allegation is that defendants failed to perform the contract.

There are, of course, exceptions to the rule that no tort recovery can lie for breach of contract. But none applies here.[4] One exception, the tort of a bad-faith breach of an insurance contract, is justified based on the "special relationship" between the insured and the insurer. That relationship is "characterized by elements

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4. The exceptions are for breaches causing physical injury, breaches of the covenant of good faith and fair dealing in insurance contracts, wrongful discharge in violation of public policy, breach where the contract was fraudulently induced, breach accompanied by a traditional common-law tort, when "the means used to breach were tortious, involving deceit or undue coercion, and when one party intentionally breaches the contract, intending or knowing that such a breach will cause severe, unmitigable harm in the form of mental anguish, personal hardship, or substantial consequential damages." *See Erlich*, 21 Cal 4th at 551-54. Given that plaintiff's fraud allegations are insufficient, none of these exceptions fits here.

of public interest, adhesion and fiduciary responsibility." Plaintiff claims that a similar relationship exists between it and defendants. However, "since . . . the insurance cases represented a major departure from traditional principles of contract law, any claim for automatic extension of that exceptional approach whenever certain hallmarks and similarities can be adduced in another contract setting should be carefully examined." *Id.* at 552-53. Here, the relationship between plaintiff and defendants does not justify bridging the divide between negligence and breach of contract.

Plaintiff argues that this relationship was special because "defendants are bound by nothing other than their honor to provide the discounts" (Opp.14). This argument is disingenuous, since plaintiff also alleges that defendants were bound by a contract. Plaintiff also relies on the foreseeability of harm if defendants negligently charged too much. Foreseeability is a factor in determining whether a tort duty exists. *See Biakanja v. Irving,* 49 Cal.2d 647, 650 (1958). "[F]oreseeability[, however,] is not synonymous with duty; nor is it a substitute." *Erlich,* 21 Cal.4th at 552. Plaintiff was free to negotiate the terms of its sales contracts with drug manufacturers. Even if there were disparities in market power between plaintiff and drug manufacturers, that would not be uncommon or sufficient to create the kind of special relationship that warrants extension of tort remedies. Furthermore, plaintiff's rights can be protected by the federal government, which may impose sanctions for overpricing. That possibility counsels against a finding that plaintiff was so vulnerable as to

be entitled to tort remedies. For these reasons, plaintiff's negligence claim is dismissed.

## 6. IN QUANTUM MERUIT.

Plaintiff brings a claim labeled "in quantum meruit." Such a claim is only viable when the plaintiff alleges that it performed a service for a defendant. *Brown v. Crown Gold Milling Co.*, 150 Cal. 376, 382 (1907); *see also* 4 B.E. Witkin, California Procedure § 527 (4th ed.1997). Plaintiff here does not allege that it provided any service to defendants. The claim therefore is dismissed.

## 7. OTHER CLAIMS AND DEFENSES.

Plaintiff's accounting claim cannot stand independently. It is merely derivative of other claims. *See Janis v. Cal. State Lottery Comm'n*, 68 Cal.App. 4th 824, 833 (Cal.Ct.App.1998); *see also Zuill v. Shanahan*, 80 F.3d 1366, 1369 (9th Cir.1996) ("The remedy they seek is a declaration that they are co-owners, and none of the subsidiary remedies, for an accounting and so forth, are independent of that remedy."). There are no viable independent claims. The accounting claim therefore fails. Even if there were viable claims, the accounting claim would not survive because no action for accounting may be maintained if there is an adequate remedy at law. *Faivre v. Daley*, 93 Cal. 664, 673 (1892); *Civic W. Corp. v. Zila Indus., Inc.*, 66 Cal.App.3d 1, 14 (Cal.Ct.App.1977). If the other claims here were viable, they would provide plaintiff with an adequate remedy at law.

Because all claims are dismissed on other grounds, there is no need to consider defendants' arguments concerning primary jurisdiction, federal preemption, real parties in interest and statues of limitations.

## CONCLUSION

For the reasons stated, defendants' motion to dismiss the second amended complaint is **G RANTED.** A prior full-scale amendment opportunity having been granted, leave to amend is not granted again. However, plaintiff(s) may have **UNTIL NOON, JUNE 2, 2006, TO FILE A MOTION SEEKING LEAVE TO A MEND.** It must be noticed on a 35-day track. Any such motion should explain specifically the proposed amendment and why it would make a difference. Failing such, final judgment shall be entered.

IT IS SO ORDERED.

## APPENDIX F — ORDER OF THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT DENYING PETITION FOR REHEARING; FILED FEBRUARY 11, 2010

## UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

No. 06-16471

D.C. No. CV-05-03740-WHA
Northern District of California, San Francisco

COUNTY OF SANTA CLARA,

Plaintiff - Appellant,

v.

ASTRA USA, INC.; ASTRAZENECA PHARMACEUTICALS LP; AVENTIS PHARMACEUTICALS, INC.; BAYER CORPORATION; BRISTOL-MYERS SQUIBB COMPANY; PFIZER, INC.; SCHERING-PLOUGH CORPORATION; TAP PHARMACEUTICAL PRODUCTS, INC.; ZENECCA INC.; ZLB BEHRING LLC; SMITHKLINE BEECHAM CORPORATION; SMITHKLINE BEECHAM CORPORATION, dba GlaxoSmithKline; WYETH, INC.; WYETH PHARMACEUTICALS, INC.,

Defendants - Appellees.

*Appendix F*

## ORDER

Before: REINHARDT, SILVERMAN and FISHER, Circuit Judges.

The panel judges have voted to deny Appellees' petition for rehearing or rehearing en banc.

The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35.

Appellees' petition for rehearing or rehearing en banc, filed December 30, 2009, is **DENIED**.

# APPENDIX G — RELEVANT STATUTES

## TITLE 42. THE PUBLIC HEALTH AND WELFARE
## CHAPTER 6A. THE PUBLIC HEALTH SERVICE
## GENERAL POWERS AND DUTIES
## PRIMARY HEALTH CARE
## DRUG PRICING AGREEMENTS

### 42 U.S.C. § 256b

**§ 256b. Limitation on prices of drugs purchased by covered entities**

**(a) Requirements for agreement with Secretary.**

**(1) In general.**

The Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer for covered drugs (other than drugs described in paragraph (3)) purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this section, does not exceed an amount equal to the average manufacturer price for the drug under title XIX of the Social Security Act [42 USCS §§ 1396 et seq.] in the preceding calendar quarter, reduced by the rebate percentage described in paragraph (2).

**(2) Rebate percentage defined.**

**(A) In general.**

For a covered outpatient drug purchased in a calendar quarter, the "rebate percentage" is the amount (expressed as a percentage) equal to—

(i) the average total rebate required under section 1927(c) of the Social Security Act [42 USCS § 1396r-8(c)] with respect to the drug (for a unit of the dosage form and strength involved) during the preceding calendar quarter; divided by

(ii) the average manufacturer price for such a unit of the drug during such quarter.

**(B) Over the counter drugs.**

**(i) In general.**

For purposes of subparagraph (A), in the case of over the counter drugs, the "rebate percentage" shall be determined as if the rebate required under section 1927(c) of the Social Security Act [42 USCS § 1396r-8(c)] is based on the applicable percentage provided under section 1927(c)(4) of such Act [42 USCS § 1396r-8(c)(4)].

**(ii) "Over the counter drug" defined.**

The term "over the counter drug" means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drug under State law).

**(3) Drugs provided under State medicaid plans.**

Drugs described in this paragraph are drugs purchased by the entity for which payment is made by the State under the State plan for medical assistance under title XIX of the Social Security Act [42 USCS §§ 1396 et seq.].

**(4) "Covered entity" defined.**

In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act [42 USCS § 1396d(l)(2)(B)]).

(B) An entity receiving a grant under section 340A [42 USCS § 256a].

(C) A family planning project receiving a grant or contract under section 1001 [42 USCS § 300].

(D) An entity receiving a grant under subpart II of part C of title XXVI [42 USCS §§ 300ff-51 et seq.] (relating to categorical grants for outpatient early intervention services for HIV disease).

(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under title XXVI [42 USCS §§ 300ff-11 et seq.].

(F) A black lung clinic receiving funds under section 427(a) of the Black Lung Benefits Act [30 USCS § 937(a)].

(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 USCS § 701(a)(2)].

(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988 [42 USCS §§ 11701 et seq.].

(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 USCS §§ 1651 et seq.].

(J) Any entity receiving assistance under title XXVI [42 USCS §§ 300ff-11 et seq.] (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).

(K) An entity receiving funds under section 318 [42 USCS § 247c] (relating to treatment of sexually transmitted diseases) or section 317(j)(2) [42 USCS § 247b(j)(2)] (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 USCS § 1395ww(d)(1)(B)]) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 USCS §§ 1395 et seq.] or eligible for assistance under the State plan under this title;

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 USCS § 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 USCS § 1395(d)(5)(F)(i)(II)]; and

(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

**(5) Requirements for covered entities.**

**(A) Prohibiting duplicate discounts or rebates.**

**(i) In general.**

A covered entity shall not request payment under title XIX of the Social Security Act [42 USCS §§ 1396 et seq.] for medical assistance described in section 1905(a)(12) of such Act [42 USCS § 1396d(a)(12)] with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act [42 USCS § 1396r-8].

**(ii) Establishment of mechanism.**

The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act [42 USCS § 1396r-8(a)(5)(C)] shall apply.

*Appendix G*

**(B) Prohibiting resale of drugs.**

With respect to any covered outpatient drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

**(C) Auditing.**

A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs [subparagraph] (A) or (B) with respect to drugs of the manufacturer.

**(D) Additional sanction for noncompliance.**

If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B), the covered entity shall be liable to the manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

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**(6) Treatment of distinct units of hospitals.**

In the case of a covered entity that is a distinct part of a hospital, the hospital shall not be considered a covered entity under this paragraph unless the hospital is otherwise a covered entity under this subsection.

**(7) Certification of certain covered entities.**

**(A) Development of process.**

Not later than 60 days after the date of enactment of this subsection [enacted Nov. 4, 1992], the Secretary shall develop and implement a process for the certification of entities described in subparagraphs (J) and (K) of paragraph (4).

**(B) Inclusion of purchase information.**

The process developed under subparagraph (A) shall include a requirement that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered outpatient drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered outpatient drugs at discounted prices.

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**(C) Criteria.**

The Secretary shall make available to all manufacturers of covered outpatient drugs a description of the criteria for certification under this paragraph.

**(D) List of purchasers and dispensers.**

The certification process developed by the Secretary under subparagraph (A) shall include procedures under which each State shall, not later than 30 days after the submission of the descriptions under subparagraph (C), prepare and submit a report to the Secretary that contains a list of entities described in subparagraphs (J) and (K) of paragraph (4) that are located in the State.

**(E) Recertification.**

The Secretary shall require the recertification of entities certified pursuant to this paragraph on a not more frequent than annual basis, and shall require that such entities submit information to the Secretary to permit the Secretary to evaluate the validity of subsequent purchases by such entities in the same manner as that required under subparagraph (B).

**(8) Development of prime vendor program.**

The Secretary shall establish a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of

covered outpatient drugs. If a covered entity obtains drugs directly from a manufacturer, the manufacturer shall be responsible for the costs of distribution.

**(9) Notice to manufacturers.**

The Secretary shall notify manufacturers of covered outpatient drugs and single State agencies under section 1902(a)(5) of the Social Security Act [42 USCS § 1396a(a)(5)] of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

**(10) No prohibition on larger discount.**

Nothing in this subsection shall prohibit a manufacturer from charging a price for a drug that is lower than the maximum price that may be charged under paragraph (1).

**(b) Other definitions.**

In this section, the terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act [42 USCS § 1396r-8(k)].

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**(c) References to Social Security Act.**

Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section [enacted Nov. 4, 1992].

**(d) Compliance with requirements.**

A manufacturer is deemed to meet the requirements of subsection (a) if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of this section (as in effect immediately after the enactment of the Veterans Health Care Act of 1992 [enacted Nov. 4, 1992]), as applied by the Secretary, and would have entered into an agreement under this section (as such section was in effect at such time), but for a legislative change in this section (or the application of this section) after the date of the enactment of such Act [enacted Nov. 4, 1992].

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# TITLE 42. THE PUBLIC HEALTH AND WELFARE
# CHAPTER 7. SOCIAL SECURITY ACT
# TITLE XIX. GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

## 42 U.S.C. § 1396r-8

### § 1396r-8. Payment for covered outpatient drugs

**(a) Requirement for rebate agreement.**

**(1) In general.**

In order for payment to be available under section 1903(a) [42 USCS § 1396b(a)] or under part B of title XVIII [42 USCS §§ 1395j et seq.] for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992 [enacted Nov. 4, 1992]) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retroactively calculated as if the agreement between the manufacturer and the State had been entered into on

January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

**(2) Effective date.**

Paragraph (1) shall first apply to drugs dispensed under this title [42 USCS §§ 1396 et seq.] on or after January 1, 1991.

**(3) Authorizing payment for drugs not covered under rebate agreements.**

Paragraph (1), and section 1903(i)(10)(A) [42 USCS § 1396b(i)(10)(A)], shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

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**(4) Effect on existing agreements.**

In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section [Nov. 5, 1990], such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title [42 USCS §§ 1396 et seq.]. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section [enacted Nov. 5, 1990] provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

**(5) Limitation on prices of drugs purchased by covered entities.**

**(A) Agreement with Secretary.**

A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the

requirements of section 340B of the Public Health Service Act [42 USCS § 256b] with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

**(B) Covered entity defined.**

In this subsection, the term "covered entity" means an entity described in section 340B(a)(4) of the Public Health Service Act [42 USCS § 256b(a)(4)] and a children's hospital described in section 1886(d)(1)(B)(iii) [42 USCS § 1395ww(d)(1)(B)(iii)] which meets the requirements of clauses (i) and (iii) of section 340B(b)(4)(L) of the Public Health Service Act [42 USCS § 256b(b)(4)(L)] and which would meet the requirements of clause (ii) of such section if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this title [42 USCS §§ 1396 et seq.].

**(C) Establishment of alternative mechanism to ensure against duplicate discounts or rebates.**

If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act [42 USCS § 256b(a)(5)(A)] within 12 months of the date of the enactment of such section [enacted Nov. 4, 1992], the following requirements shall apply:

**(i) Entities.**

Each covered entity shall inform the single State agency under section 1902(a)(5) [42 USCS § 1396a(a)(5)] when it is seeking reimbursement from the State plan for medical assistance described in section 1905(a)(12) [42 USCS § 1396d(a)(12)] with respect to a unit of any covered outpatient drug which is subject to an agreement under section 340B(a) of such Act [42 USCS § 256b(a)].

**(ii) State agency.**

Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 340B of such Act [42 USCS § 256b], and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

**(D) Effect of subsequent amendments.**

In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act [42 USCS § 256b], the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992 [enacted Nov. 4, 1992].

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**(E) Determination of compliance.**

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 340B of the Public Health Service Act [42 USCS § 256b] (as in effect immediately after the enactment of this paragraph [enacted Nov. 4, 1992]) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

**(6) Requirements relating to master agreements for drugs procured by department of veterans affairs and certain other Federal agencies.**

**(A) In general.**

A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, United States Code, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

**(B) Effect of subsequent amendments.**

In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, United States Code, the

Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992 [enacted Nov. 4, 1992].

**(C) Determination of compliance.**

A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, United States Code (as in effect immediately after the enactment of this paragraph) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

**(7) Requirement for submission of utilization data for certain physician administered drugs.**

**(A) Single source drugs.**

In order for payment to be available under section 1903(a) [42 USCS § 1396b(a)] for a covered outpatient drug that is a single source drug that is physician administered under this title [42 USCS §§ 1396 et seq.] (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National

Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this title [42 USCS §§ 1396 et seq.].

**(B) Multiple source drugs.**

**(i) Identification of most frequently physician administered multiple source drugs.**

Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this title [42 USCS §§ 1396 et seq.]. The Secretary may modify such list from year to year to reflect changes in such volume.

**(ii) Requirement.**

In order for payment to be available under section 1903(a) [42 USCS § 1396b(a)] for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

**(C) Use of NDC codes.**

Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

**(D) Hardship waiver.**

The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

**(b) Terms of rebate agreement.**

**(1) Periodic rebates.**

**(A) In general.**

A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title [42 USCS §§ 1396 et seq.], a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

**(B) Offset against medical assistance.**

Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1) [42 USCS § 1396b(a)(1)].

**(2) State provision of information.**

**(A) State responsibility.**

Each State agency under this title [42 USCS §§ 1396 et seq.] shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

**(B) Audits.**

A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

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**(3) Manufacturer provision of price information.**

**(A) In general.**

Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement—

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(c)]); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(c)]), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990[,] for each of

the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(c)]); and

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

(I) the manufacturer's average sales price (as defined in section 1847A(c) [42 USCS § 1395w-3a(c)]) and the total number of units specified under section 1847A(b)(2)(A) [42 USCS § 1395w-3a(b)(2)(A)];

(II) if required to make payment under section 1847A [42 USCS § 1395w-3a], the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

(III) information on those sales that were made at a nominal price or otherwise described in section 1847A(c)(2)(B) [42 USCS § 1395w-3a(c)(2)(B)];

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) [42 USCS § 1395u(o)(1)] or section 1881(b)(13)(A)(ii) [42 USCS § 1395rr(b)(13)(A)(ii)], and, for calendar quarters beginning on or after January 1, 2007 and only with

respect to the information described in subclause (III), for covered outpatient drugs.

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v).

**(B) Verification surveys of average manufacturer price and manufacturer's average sales price.**

The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed $100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A [42 USCS § 1320a-7a] (other than subsections (a) (with respect to

amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [42 USCS § 1320a-7a(a)].

**(C) Penalties.**

**(i) Failure to provide timely information.**

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by $ 10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of the 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

**(ii) False information.**

Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed $ 100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A [42 USCS § 1320a-7a] (other than subsections

(a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a) [42 USCS § 1320a-7a(a)].

**(D) Confidentiality of information.**

Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) (other than the wholesale acquisition cost for purposes of carrying out section 1847A [42 USCS § 1395w-3a]) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1847A [42 USCS § 1395w-3a] (including the determination and implementation of the payment amount), or to carry out section 1847B [42 USCS § 1395w-3b],

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this title [42 USCS §§ 1396 et seq.], and

(v) to the Secretary to disclose (through a website accessible to the public) average manufacturer prices.

The previous sentence shall also apply to information disclosed under section 1860D-2(d)(2) or 1860D-4(c)(2)(E) [42 USCS § 1395w-102(d)(2) or 1395w-104(c)(2)(E)] and drug pricing data reported under the first sentence of section 1860D-31(i)(1) [42 USCS § 1395w-141(i)(1)].

**(4) Length of agreement.**

**(A) In general.**

A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

**(B) Termination.**

**(i) By the Secretary.**

The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The

Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

**(ii) By a manufacturer.**

A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

**(iii) Effectiveness of termination.**

Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

**(iv) Notice to States.**

In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

**(v) Application to terminations of other agreements.**

The provisions of this subparagraph shall apply to the terminations of agreements described in section 340B(a)(1) of the Public Health Service Act [42 USCS § 256b(a)(1)] and master agreements described in section 8126(a) of title 38, United States Code.

**(C) Delay before reentry.**

In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

**(c) Determination of amount of rebate.**

**(1) Basic rebate for single source drugs and innovator multiple source drugs.**

**(A) In general.**

Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price, for the rebate period.

**(B) Range of rebates required.**

**(i) Minimum rebate percentage.**

For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; and

(V) after December 31, 1995, is 15.1 percent.

**(ii) Temporary limitation on maximum rebate amount.**

In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

**(C) Best price defined.**

For purposes of this section—

**(i) In general.**

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(c)]), the lowest price available from the manufacturer during the rebate period to any

wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act [42 USCS § 256b(a)(4)(L)]);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D-31 [42 USCS § 1395w-141]; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII

[42 USCS §§ 1395w-101 et seq.], by an MA-PD plan under part C of such title [42 USCS §§ 1395w-21 et seq.] with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2) [42 USCS § 1395w-132(a)(2)]) with respect to such drugs on behalf of individuals entitled to benefits under part A [42 USCS §§ 1395c et seq.] or enrolled under part B of such title [42 USCS §§ 1395j et seq.].

**(ii) Special rules.**

The term "best price"—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 USCS § 355(c)], shall be inclusive of the lowest price for

such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

**(iii) Application of auditing and recordkeeping requirements.**

With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act [42 USCS § 256b(a)(4)(L)], any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act [42 USCS § 256b(a)(5)(C)].

**(D) Limitation on sales at a nominal price.**

**(i) In general.**

For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 340B(a)(4) of the Public Health Service Act [42 USCS § 256b(a)(4)].

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

**(ii) Factors.**

The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

**(iii) Nonapplication.**

Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, United States Code [38 USCS § 8126].

**(2) Additional rebate for single source and innovator multiple source drugs.**

**(A) In general.**

The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city

average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

**(B) Treatment of subsequently approved drugs.**

In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting "the first full calendar quarter after the day on which the drug was first marketed" for "the calendar quarter beginning July 1, 1990" and "the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed" for "September 1990".

**(3) Rebate for other drugs.**

**(A) In general.**

The amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

**(B) Applicable percentage defined.**

For purposes of subparagraph (A)(i), the "applicable percentage" for rebate periods beginning—

(i) before January 1, 1994, is 10 percent, and

(ii) after December 31, 1993, is 11 percent.

* * * *

## APPENDIX H — PHARMACEUTICAL PRICING AGREEMENT

**PHARMACEUTICAL PRICING AGREEMENT**
**(hereinafter referred to as the "Agreement")**
**Between**
**THE SECRETARY OF HEALTH AND HUMAN SERVICES**
**(hereinafter referred to as the "Secretary")**
**and**
**THE MANUFACTURER**
**Identified in Section IX of this Agreement**
**(hereinafter referred to as the "Manufacturer")**

The Secretary, on behalf of the Department of Health and Human Services, and the Manufacturer for purposes of section 602 of the Veterans Health Care Act of 1992, Public Law No. 102-585, which enacted section 340B of the Public Health Service Act (hereinafter referred to as "the Act"), 42 U.S.C. 256b, hereby agree to the following:

### I. *Definitions*

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in the Act and section 1927(k) of the Social Security Act, as interpreted and applied herein:

(a) ***"Average Manufacturer Price (hereinafter referred to as the "AMP")"*** means the average unit price paid to the Manufacturer for the drug in all States by wholesalers for drugs distributed to the retail pharmacy class of

trade, after deducting customary prompt pay discounts (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under the distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Social Security Act), which reduce the actual price paid. It is calculated as a weighted average of each drug of prices for all the Manufacturer's package sizes for each calendar quarter. Specifically, it is calculated as net sales divided by the numbers of units sold, excluding free goods (i.e., drugs or any other items given away, but not contingent on any purchase requirements). For bundled sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangements. The AMP for a calendar quarter must be adjusted by the Manufacturer, if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) ***"Best Price"*** has the meaning given it in section 1927(c)(1)(C) of the Social Security Act, and section I(d) of the Medicaid Rebate Agreement.

(c) ***"Bundled Sale"*** refers to the packaging of drugs of different types where the total price for the package is less than the purchase price of the drugs, if purchased separately.

(d) ***"Covered Drug"*** means an outpatient drug as set forth in section 1927(k) of the Social Security Act. For purposes of coverage under the Agreement, all covered outpatient drugs are identified by the NDC number.

(e) ***"Covered Entity"*** means:

(1) certain Public Health Service grantees, "look-alike" Federally Qualified Health Centers and disproportionate share hospitals as described in section 340B(a)(4) of the Act; and

(2) in the case of a covered entity that is a distinct part of a hospital, the hospital itself shall not be considered a covered entity unless it meets the requirements of section 340B(a)(4)(L) of the Act, as determined by the Secretary.

(f) ***"Manufacturer"*** has the meaning as set forth in section 1927(k)(5) of the Social Security Act except that, for purposes of the Agreement, it shall also mean the entity holding legal title to

or possession of the NDC number for the covered outpatient drug. The term includes:

(1) any Manufacturer who sells covered outpatient drugs to covered entities, whether or not the Manufacturer participates in the Medicaid rebate program; and

(2) any contractors which fulfill the responsibilities pursuant to the Agreement, unless excluded by the Secretary.

(g) ***"Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration)"*** means the agency of the Department of Health and Human Services having the delegated authority to administer the Medicaid and Medicare Programs.

(h) ***"Medicaid Rebate Program and Medicaid Rebate Agreement"*** mean, respectively, the program, and a signed agreement between the Secretary and the Manufacturer, to implement the provisions of section 1927 of the Social Security Act.

(i) ***"National Drug Code (NDC)"*** means the identifying drug number maintained by the Food and Drug Administration (FDA). For purposes of the Agreement, the NDC number

will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specified product or formulation), and package size code when reporting requested information.

(j) ***"Over the Counter Drug"*** means a drug that may be sold without a prescription and which is prescribed by a physician (or other persons authorized to prescribe such drugs under State law).

(k) ***"Quarter"*** means a calendar quarter unless otherwise specified.

(l) ***"Rebate Percentage"*** means an amount (expressed in a percentage) equal to the average total rebate required under section 1927(c) of the Social Security Act with respect to each dosage, form, and strength of a single source or innovator multiple source drug during the preceding calendar quarter; divided by the AMP for such a unit of the drug during such quarter.

(m) ***"the Secretary"*** means the Secretary of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(n) ***"Unit of the Drug"*** means a drug unit in the lowest identifiable amount (e.g., tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each covered outpatient drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Section II of the Agreement.

(o) ***"Wholesaler"*** means any entity, having a wholesale distributor's license, to which a Manufacturer sells the covered outpatient drug, but which does not relabel or repackage the covered outpatient drug.

## II. MANUFACTURER'S RESPONSIBILITIES

Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:

(a) for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage;

(b) for multiple source, noninnovator multiple source, and over the counter drugs, the AMP is reduced by 11%, as described in 1927(c)(3)(B)(ii) of the Social Security Act;

(c) for those Manufacturers that do not have a reporting requirement under section 1927(b)(3) of the Social Security Act for covered outpatient drugs, to submit to the Secretary upon request, a list of such covered outpatient drugs, and the AMP, baseline AMP, and the Best Price of such covered outpatient drugs;

(d) to retain all records that may be necessary to provide the information described in paragraph (c) of this section for not less than 3 years from the date of their creation;

(e) to afford the Secretary or his designee reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement;

(f) to permit CMS to share AMP and unit rebate amount submitted under the Medicaid Rebate Agreement on covered outpatient drugs with the Secretary or his designee for purposes of carrying out the Agreement; and

(g) to participate in the HRSA Prime Vendor Program as provided by section 340B(a)(8) of the Act unless otherwise agreed to by the Secretary.

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## III. SECRETARY'S RESPONSIBILITIES

Pursuant to the requirements under section 340B of the Act, the Secretary agrees to the following:

(a) to make available a list of covered entities on the HRSA, Office of Pharmacy Affairs web site (http://www.bphc.hrsa.gov/opa/), or otherwise, for access by participating Manufacturers, covered entities, State Medicaid agencies, and the general public. This information will be updated, to the extent practicable, on a quarterly basis;

(b) with respect to a covered entity that bills Medicaid using a cost basis for drug purchases, to require the entity to submit its pharmacy Medicaid provider number. The Secretary shall provide respective State Medicaid agencies with the list of such entities and their Medicaid provider numbers. Based on these provider numbers, the State agencies will create an exclusion file which will exclude data from these entities when generating Medicaid rebate requests.

(c) to require each covered entity to retain purchasing and dispensing records of covered outpatient drugs under the Agreement and of any claims for reimbursement submitted for such drugs under Title XIX of the Social Security Act for not less than 3 years.

*Appendix H*

## IV. DISPUTE RESOLUTION

(a) If the Manufacturer believes that a covered entity has violated the prohibition against resale or transfer of covered outpatient drugs, section 340B(a)(5)(B), or the prohibition against duplicate discounts or rebates, section 340B(a)(5)(A), the Manufacturer can access the elective dispute resolution process in the following manner:

(1) The Manufacturer shall attempt in good faith to resolve the matter with the covered entity.

(2) If unable to resolve the dispute, the Manufacturer may provide written notice of the discrepancy to the Secretary.

(3) The Secretary, at his discretion, will initiate an informal dispute resolution process.

(4) If the Secretary finds, after conclusion of the dispute resolution process, that the entity is in violation of such prohibitions, the entity shall be liable to the Manufacturer of the covered outpatient drug that is the subject of the violation in an amount equal to the reduction in the price of the drug as

described in section II(a) of the Agreement. Pursuant to section 340B(a)(4) and (5) a covered entity also could be removed from the list of eligible entities.

(b) The Manufacturer may challenge the presence of an entity on the list of eligible entities issued by the Secretary. Upon presentation of appropriate information documenting the entity's ineligibility, the Secretary shall take such steps as necessary to carry out his responsibilities under paragraph III(a) of the Agreement.

(c) If the Secretary believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate the Agreement. A Manufacturer who does not have an agreement with the Secretary pursuant to the Act, will no longer be deemed to meet the requirements of section 1927(a)(5)(A) of the Social Security Act.

(d) A covered entity's failure to comply with the audit requirement pursuant to section

340B(a)(5)(C) of the Act shall be cause for the Manufacturer to notify the Secretary or his designee and for the Secretary to initiate the informal dispute resolution process. Such action will not relieve the Manufacturer from its obligation to conform to the pricing requirements as provided in section 340B(a) of the Act and the Agreement.

(c) Nothing in this paragraph shall preclude the Manufacturer or the Secretary from exercising such other remedies as may be available by law.

## V. CONFIDENTIALITY PROVISIONS

(a) Information disclosed by the Manufacturer in connection with the Agreement, except as otherwise required by law, will not be disclosed by the Secretary or his designee in a form which reveals the Manufacturer, except as necessary to carry out the provisions of section 340B of the Act, and to permit review by the Comptroller General.

(b) The Manufacturer will hold audit information obtained from the covered entities confidential. If the Manufacturer receives further information on such data, that information shall also be held confidential. Nothing in this paragraph shall preclude the Manufacturer

from making such information available to the Secretary to enable the Secretary to carry out the provisions of section 340B of the Act.

## VI. NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of the Agreement, the Agreement shall be effective for an initial period of 1 year, beginning on the date specified in section IX of the Agreement. It shall be automatically renewed for additional successive terms of 1 year unless the Manufacturer gives written notice of intent not to renew the Agreement at least 90 days before the end of the applicable period.

(b) The Manufacturer may terminate the Agreement for any reason. Such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, and the ending date of the term of the Agreement, if notice has been given 90 days before the end of the term.

(c) The Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide the Manufacturer, upon request,

the opportunity to participate in an informal dispute resolution process concerning the termination, but such a process shall not delay the effective date of the termination. Disputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract. Actions taken by the parties in such disputes are not grounds for termination of the Agreement with the Secretary, except to the extent that there is a violation of the provisions of the Agreement.

(d) If the Agreement is not renewed or is terminated, the Manufacturer is prohibited from entering into another Agreement as provided in section 340B of the Act until a period of one complete calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect the ceiling price under paragraph II(a) for any covered outpatient drug purchased before the effective date of termination.

*Appendix H*

## VII. GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of the Agreement will be sent in writing.

(1) Notice to the Secretary will be sent to:

Healthcare Systems Bureau
Office of Pharmacy Affairs
5600 Fishers Lane
Mail Stop 10C-03
Rockville, Maryland 20857

(2) Notice concerning data transfer and information systems issues is to be sent to the same address as listed above (section VII(a)(1) of this Agreement).

(3) Notice to the Manufacturer will be sent to the address as provided with the Agreement and updated upon Manufacturer notification to the Secretary at the address in the Agreement.

(b) The Manufacturer will be permitted to audit the records of each covered entity

(1) that directly pertain to the entity's compliance with the prohibition on

(A) the resale or other transfer of covered outpatient drugs to persons not patients of the entity, section 340B(a)(5)(B), and

(B) duplicate discounts pertaining to the rebate under section 1927 of the Social Security Act, section 340B(a)(5)(A);

(2) in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits; and

(3) at the Manufacturer's expense.

(c) No provision in the Agreement shall prohibit the Manufacturer from charging a price for a drug that is lower than the ceiling price as described in section II(a) of the Agreement.

(d) In the event of a transfer in ownership of the Manufacturer, the Agreement is automatically assigned to the new owner.

(e) Nothing in the Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of the Agreement is found to be invalid by a court of law, the Agreement will be construed in all

respects as if any invalid or unenforceable provisions were eliminated, and without any effect on any other provision.

(f) Nothing in the Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, or Federal laws, or State laws.

(g) The Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(h) Except for changes of addresses, the Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(i) In the event that a due date falls on a weekend or Federal holiday, items will be due on the first business day following that weekend or Federal holiday.

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## VIII. EFFECTIVE DATE

The Agreement will be effective upon signing but will in no way alter the effective date upon which drug discounts were to be given to covered entities under any previously signed Pharmaceutical Pricing Agreement between the Secretary and the Manufacturer.

# OPPOSITION BRIEF

No. 09-1273

IN THE

# Supreme Court of the United States

ASTRA USA, INC.; ASTRAZENECA PHARMACEUTICALS LP; AVENTIS PHARMACEUTICALS, INC.; BAYER CORP.; BRISTOL-MYERS SQUIBB CO.; PFIZER, INC.; SCHERING-PLOUGH CORP.; SMITHKLINE BEECHAM CORP.; TAP PHARMACEUTICAL PRODUCTS, INC.; WYETH, INC.; WYETH PHARMACEUTICALS, INC.; ZENECA INC.; AND ZLB BEHRING LLC,
*Petitioners,*

v.

THE COUNTY OF SANTA CLARA, On Behalf of Itself and All Others Similarly Situated,
*Respondent.*

**On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI


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## QUESTION PRESENTED

The question framed by the petition does not accurately characterize respondent's cause of action or the Court of Appeals' decision. As the Court of Appeals held, this action is subject to federal contract law which, consistent with this Court's precedents, allows respondent to bring a third-party claim for breach of a government contract that is explicitly "'intended for his direct benefit.'" *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303, 307 (1927); *County of Santa Clara v. Astra, USA, Inc.*, 588 F.3d 1237, 1243-45 (9th Cir. 2009). Indeed, the Court of Appeals assumed that §340B, "[42 U.S.C.] §256b does not create a private cause of action." *Id.* at 1249 n.15.

This Court has emphasized that "private parties in appropriate cases may sue in federal court to enforce contractual rights created by federal statutes," a principle which is discrete from and "does not fit comfortably in [the] mold" of implied private right of action cases. *Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union, AFL-CIO-CLC*, 457 U.S. 15, 20, 22 (1982). Accordingly, the question presented is:

Whether the Court of Appeals correctly concluded that §340B does not displace a claim for breach of the contract it mandates between the federal government and petitioning drug manufacturers and that, under the federal common law of contracts, the "covered entities" who are the intended direct beneficiaries of that contract may sue petitioners for breach of their contractual obligations to cap the prices at which they sell drugs to covered entities?

## PARTIES

Respondents are the County of Santa Clara, California, on behalf of its §340B (42 U.S.C. §256b) "covered entities," including a public hospital and associated clinics that the County funds, and the County of Santa Cruz, California, individually, and as representatives of all other similarly situated, covered-entity medical facilities, who allege they were overcharged for drugs in breach of the ten petitioning drug manufacturers' pharmaceutical pricing agreements with the government.

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IN THE

# Supreme Court of the United States

No. 09-1273

ASTRA USA, INC.; ASTRAZENECA PHARMACEUTICALS LP; AVENTIS PHARMACEUTICALS, INC.; BAYER CORP.; BRISTOL-MYERS SQUIBB CO.; PFIZER, INC.; SCHERING-PLOUGH CORP.; SMITHKLINE BEECHAM CORP.; TAP PHARMACEUTICAL PRODUCTS, INC.; WYETH, INC.; WYETH PHARMACEUTICALS, INC.; ZENECA INC.; AND ZLB BEHRING LLC,
*Petitioners,*

v.

THE COUNTY OF SANTA CLARA, On Behalf of Itself and All Others Similarly Situated,
*Respondent.*

**On Petition for Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

## INTRODUCTION

Petitioners, ten drug manufacturers ("Drugmakers"), attempt to create a conflict among the circuits by conflating a body of law that delineates the circumstances in which courts may recognize an implied private right of action under statute, with the distinct body of decisions consistently establishing that an intended third-party beneficiary of a government con-

tract may sue *on the contract* to enforce obligations for its direct benefit. This case addresses who is entitled to enforce a claim for breach of contract resulting from overcharges in violation of the petitioning drug manufacturers' agreement to cap the prices they charge to the covered entities that make up a critical part of the nation's healthcare safety net. There is no need to resort to implied right of action doctrine. Contrary to the petition, this case does not involve a free-standing federal common law claim. (Petition ("Pet.") 2-4) Rather, this Court's decisions plainly authorize respondent's suit to enforce the contract obligation that Congress mandated by statute for respondent's direct benefit.

The Second Amended Complaint ("Complaint") alleges, based on a series of reports from the Office of Inspector General of the Department of Health and Human Services ("OIG"), that, in breach of the contract created by §340B (42 U.S.C. §256b), Drugmakers have overcharged 97% of covered entities like respondent for drugs since 1999, and that such overcharging continues unchecked and is substantial. (ER 14-15¶¶4-7)[1] Several of the petitioning Drugmakers have pled guilty to violating Medicaid drug pricing requirements – but §340B has not been similarly enforced. (ER 418-20) AstraZeneca entered a plea of guilty in 2003 for violating various other drug pricing requirements and agreed to pay a $355 million fine. (ER 34¶67) Pfizer paid $9 million in 2002 to settle violations of a Medicaid rebate program. (ER 34¶68) In 2001, TAP Pharmaceutical Products paid $875 million in fines – $559.5 million for violating

[1] All references to "ER" and "SER" refer to the Excerpts of Record and Supplemental Excerpts of Record filed in the second appeal in this case, Ninth Cir. 09-15216.

Medicaid best pricing requirements similar to those in §340B. (ER 34¶69) Petitioners did not petition this Court until the lower courts' rulings made clear that they would have to produce documents revealing how they calculated drug pricing in violation of the 340B contract.

The fact that the federal law of contracts – like the Restatement and the law of many states – provides that an intended direct third-party beneficiary may enforce a breach of contract does not mean that "general federal common law" is being invoked to create a cause of action out of whole cloth. In this case, the Court of Appeals assumed without deciding that §340B does not by implication authorize a private right of action. Petitioners contend that in the absence of an implied statutory remedy, there can be no right to enforce their contractual obligations to the government. They do not dispute their obligations under the contracts, nor do they dispute here that respondents are intended direct third-party beneficiaries of the contract. Instead, petitioners assert that applying basic principles of contract law is somehow inconsistent with this Court's prescribed limitations on implied rights of action under statute.

Contrary to the petition, respondent, the County of Santa Clara ("Santa Clara" or "County") need not depend on an implied private right of action under §340B. Instead, the County sued for breach of the contract created by §340B. The Court of Appeals held that the County has the right to sue for breach of the government contract created by §340B – the pharmaceutical pricing agreement ("PPA" or "Contract") – a contract expressly intended for the direct benefit of the County's "covered entity" medical facilities. As the Court of Appeals concluded: "[W]e

are unable to discern any substantial purpose of the PPA *other* than to grant eligible covered entities a discount on covered drugs." *County of Santa Clara v. Astra, U.S.A., Inc.*, 588 F.3d 1237, 1246 (9th Cir. 2009) ("*Santa Clara II*") (emphasis in original). There is nothing novel in this holding.

This Court has long held that "private parties may sue in federal court to enforce contractual rights created by federal statutes" that "lacked express provisions creating federal causes of action." *Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union, AFL-CIO CLC*, 457 U.S. 15, 22 (1982). This Court has already concluded that a suit to enforce a government contract is different from and "does not fit comfortably in [the] mold" of a statutory implied private right of action. *Id.* at 22, 29-30. Similarly, here the "gist of the [County's] position is not that the [statute] creates an implied right of action to sue for violation of the statute." *Id.* at 21. Instead, the County seeks to vindicate the rights of its covered entities under contracts intended for their direct benefit that were created by a federal statute which expressly provides them no remedy other than enforcement of the contract itself.

Consistent with this Court's longstanding contract law jurisprudence, respondents sued the Drugmakers as third-party beneficiaries of the government contract because it "'was intended for [their] direct benefit.'" *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303, 307 (1927); *German Alliance Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220, 230 (1912); *Boyle v. United Techs. Corp.*, 487 U.S. 500, 505 (1988) (recognizing "liability to third persons" that "arises out of performance of the [government] contract" as a "'uniquely federal' interest").

The asserted conflict among the circuits does not exist. Petitioners' purported conflict mistakenly conflates cases involving statutory displacement of contract claims (which they wrongly characterize as implied right of action cases) from three circuits with third-party beneficiary contract cases in five other circuits. In all of these cases, the courts held that plaintiff could not sue, either because there was no implied right of action under statutes which provided administrative remedies (three circuits), or because the plaintiff was merely an incidental beneficiary of the contract (five circuits). Here, petitioners do not dispute the Court of Appeals' decision that respondent is the *intended direct beneficiary* of the contract, and the statute creating the contract provided *no administrative remedy*.

Petitioners' assertion that there is no general federal common law does not negate the Court of Appeals' holding that respondents are entitled to sue on a contract as intended direct third-party beneficiaries. This Court has long recognized that government contracts created by statute and involving "uniquely federal interests" can be enforced in federal court. *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366-67 (1943); *United States v. Little Lake Misere Land Co.*, 412 U.S. 580, 592-94 (1973); *United States v. Kimbell Foods, Inc.*, 440 U.S. 715, 726-29 (1979). Whether the court applies federal common law as the contract provides, or state contract law, the choice of law does not affect the right to sue to enforce the contract. Indeed, while petitioners' *amici* simply rehash the petition's contentions, the Chamber of Commerce candidly concedes that this Court recognizes an exception to *Erie* for suits enforcing federal contracts. (*See Amicus* Brief at 8)

In sum, certiorari should be denied here because the question raised by Drugmakers' petition is not presented here. This is not an implied statutory private right of action case; this is a breach of federal contract case. There is no circumvention of implied right of action jurisprudence. The asserted circuit split does not exist.

## STATEMENT OF THE CASE

Section 340B created a contractual mechanism requiring drug manufacturers that benefit from participating in Medicaid to sell drugs at discounted prices to "covered entities" that treat indigent Medicaid patients. 42 U.S.C. §256b(a)(1); *Univ. Med. Ctr. v. Shalala*, 173 F.3d 438, 439 (D.C. Cir. 1999). As the government's *amicus* brief in the Court of Appeals explained ("U.S. Br."), §340B was enacted in 1992 when "Congress became concerned that [drug] manufacturers were overcharging safety-net providers such as public hospitals, community health clinics, and similar [now-covered] entities." (U.S. Br. at 7, published in 2009 WL 4089524 (U.S. Oct. 27, 2009))[2]

### A. Section 340B Requires Drugmakers to Contract with the Secretary to Provide Drugs at Discount Prices to Covered Entities

Section 340B provides, in relevant part:

> The Secretary [of Health and Human Services] shall enter into an agreement with each manufacturer of covered outpatient drugs under which the amount required to

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[2] The pagination to the U.S. Br. is to the printed Westlaw version.

> be paid (taking into account any rebate or discount, as provided by the Secretary) to the manufacturer . . . by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug. . . reduced by [a] rebate percentage . . . .

42 U.S.C. §256b(a)(1). The contract provides that its terms "shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." (ER 58(g)) On behalf of the Secretary, the §340B program is monitored by the Health Resources and Services Administration ("HRSA") within HHS. (ER 24¶34)

The plain language of the Contract expresses the clear intent of the contracting parties that Drugmakers charge "covered entities" like Santa Clara's medical facilities – no more than a discount or "ceiling" price for covered drugs as prescribed by the statute:

> Pursuant to requirements under section 340B of the Act, the Manufacturer agrees to the following:
>
> (a) . . . to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP [Average Manufacturer Price] for the covered outpatient drug reported . . . to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) . . . reduced by the rebate percentage.

(ER 53) The petitioning Drugmakers – which enjoy annual sales ranging from $5.8 billion to $16.5 billion (ER 18-23¶¶15-29) – entered into a §340B Contract with Santa Clara (ER 40¶¶102-103), and agreed to

sell drugs to the County's covered entities at discount prices as a condition of participating in and being paid by Medicaid. (ER 25¶38) The standardized Contract between the Secretary and the Drugmakers is attached to the Complaint. (ER 49-59)

Apart from the Contract itself which allows "such other remedies as may be available by law" (ER 56), §340B provides no remedies to covered entities to recover for being overcharged by Drugmakers. The statute does, however, provide that "The Secretary shall establish a mechanism to ensure that covered entities comply" with a provision prohibiting duplicate discounts. 42 U.S.C. §256b(a)(5)(A)(ii). The Secretary established such a mechanism allowing drug manufacturers to access the agency's elective dispute resolution process to recover from covered entities for any duplicate discounts made. (ER 55) But the Secretary's regulations expressly provide that no "covered entity is required to avail itself of this [agency dispute resolution] process before resorting to other available remedies." Manufacturer Audit Guidelines – Dispute Resolution Process 0905-2A-19, 61 Fed. Reg. 65406, 65411 (Dec. 12, 1996).

### B. Under the Contracts Created by §340B, Covered Entities Are Entitled to Drugs at a Ceiling Price Computed from the Correctly Reported Average Manufacturer Price and Best Price

As the district court observed, under the Contract, the §340B ceiling price per unit is calculated by the following simple formula: "AMP [minus] Unit Rebate Amount ["URA"] = Ceiling Price[.] 42 U.S.C. 256b (a)(1)-(2)." (ER 5) In turn, the URA formula is the

"greater" of AMP minus BP, or 15.1% of AMP, as spelled out by the district court:

> The average manufacturer's price ("AMP") is (simplifying slightly) just the average price paid to the manufacturers by wholesalers in the United States. 42 U.S.C. 1396r-8(b)(3)(A), (k)(1). The unit rebate amount ("URA") is, in some circumstances, just a fixed percentage of the AMP, and in others is the AMP minus the 'best price,' term defined as (again simplifying slightly) the manufacturers' best price charged to wholesalers, with certain exclusions. 42 U.S.C. 1396r-8(c). Both the AMP and the 'best price' are calculated or collected *by the manufacturers* and are then simply *reported to* the Secretary. *Id.* at §1396r-8(b)(3)(A).

(ER 5-6)[3] As defined in the Contract, the AMP is an "average" unit price for each drug sold. (ER 51, 406-07) The data underlying that reported number includes all of the unit prices each manufacturer charged to its wholesalers for a specific drug during the previous quarter. They must retain a record of prices underlying AMP and "best price" data for ten years. 42 C.F.R. §447.510.

By contrast, "best price" ("BP") is simply the "lowest price available from the manufacturer" that the manufacturer charged to any of its customers during the prior quarter and requires no calculation. 42 U.S.C. §1396r-8(c)(1)(C)(i). Thus, to determine the correct ceiling price, Santa Clara must assess all of the manufacturer prices for a given drug both to

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[3] Citations and footnotes are omitted and emphasis is added unless otherwise noted.

determine the average and to determine which is the "lowest" or "best" price. To put it mathematically, Ceiling Price = AMP – (AMP – BP) = BP. In other words, the ceiling price is typically the best price.

### C. When the Correct Best Price Is Lower than the Reported Best Price, the §340B Ceiling Price Decreases and Medicaid Rebates Increase – a Win-Win Result for Both States and Covered Entities

The OIG reports in the record reveal that typically it is the manufacturers' overstatement of BP that causes both lower Medicaid rebates to the States and overcharges to covered entities in excess of the correct ceiling price for drugs purchased under the §340B program. (ER 14-15¶4; ER 64-67) Indeed, Drugmakers unwittingly conceded in their Court of Appeals brief ("DB") that BP is the component of the formula where they try to evade use of "a single low price transaction" that "could create a significant rebate liability to Medicaid." (DB 16)[4]

It is also evident that when actual BPs are lower than the BPs inaccurately *reported* by the manufacturers, as alleged, the results would benefit both covered entities in the form of lower ceiling prices and the States in the form of higher Medicaid rebate amounts. Thus, both the Medicaid and 340B programs

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[4] Reported cases likewise reveal the manufacturers' efforts to evade BP requirements. *E.g.*, *Steinke v. Merck & Co.*, 432 F. Supp. 2d 1082, 1086-87 (D. Nev. 2006) (Upholding complaint challenging manufacturer's calculation of BP); *Mass. v. Mylan Labs.*, 357 F. Supp. 2d 314, 329 (D. Mass. 2005) (held state can sue as intended third-party beneficiary of Medicaid rebate agreement any "'manufacturer that failed to calculate its best price obligations in accordance with the Rebate Agreement or CMS guidance'").

benefit from correct lower BP submissions. Both programs gain from accurate data; there are no antagonistic results as petitioners claim. (Pet. 25-26)

Further, contrary to petitioners' assertion (*Id.* 25), covered entities do not benefit when the correct AMP is lower than the AMP reported. The URA under Medicaid would be lower when the correct AMP is lower than that reported, but as the district court in this case recognized:

> If defendants have *not* committed significant reporting errors, there should be no widespread impact on the Medicaid rebate program, and if defendants *have* systematically misreported data to the Medicaid program, defendants fail to explain why it would be undesirable (for anyone other than defendants) for such conduct to come to light.

(ER 9, emphasis in original) As the government's *amicus* brief in the Court of Appeals acknowledged, drug manufacturers cannot comply with the contract using just any pricing data they reported. They must use "accurately reported AMP and best price" data. (U.S. Br. at 10-11)

### D. As Inspector General Reports Reveal, Drugmakers Have Consistently Overcharged 97% of Covered Entities Millions of Dollars Since 1999 in Breach of Their Agreement to Cap Drugs at Discount Prices

In combination, covered entities spent $3.4 billion on drugs in 2003. (ER 14¶2) Santa Clara §340B medical facilities spent $29 million in 2003, $30 million in 2004, and $31 million for the first eight months of 2005. (ER 14¶3)

The Complaint alleges, based on a series of reports from the OIG, that, in breach of the §340B Contract, Drugmakers have overcharged 97% of covered entities like respondent for drugs since 1999, that such overcharging continues unchecked, and that it is substantial. (ER 14-15¶¶4-7) A 2003 OIG report revealed there were $6.1 million in overcharges in 1999 by five manufacturers for just 11 drugs surveyed. (ER 14-15¶4; 67; 420; 430 n.17) The overcharges occurred because drug manufacturers incorrectly excluded certain low-price sales "from their best price determinations, thereby increasing the prices charged to 340B entities." (ER 64-67) In 2004, HRSA asked the five manufacturers to refund the $6.1 million in §340B overcharges for 1999; a year later no refunds had been issued. (ER 14-15¶4; 420; 430 n.17) As noted above, several Drugmakers have paid hundreds of millions in fines to Medicaid – but §340B has not been similarly enforced. (ER 34, 418-20)

A June 2004 OIG report found that in one month, September 2002, there were $41.1 million in overcharges. (*Id.*) Thus, extrapolating for the entire year, the OIG estimated there were nearly $500 million in overcharges in 2002. (*Id.*) Although the June 2004 OIG report was withdrawn in October 2004 to correct the data concerning overcharges, the withdrawal reaffirmed that the pricing problems found still exist:

> "Despite our withdrawal of the Report because of problems with the underlying data, we continue to believe there are systemic issues that lead to price discrepancies within the 340B Drug Pricing Program. These newly-discovered data problems do not affect the validity of three findings of the Report."

(ER 32-33¶63) The three findings reaffirmed by the OIG, and embodied in the Complaint, are: (i) there is weak or non-existent agency oversight of drug pricing and no process "to confirm that §340B entities receive the ceiling price"; (ii) covered entities have no means to "verify" whether they are being charged the correct price due to manufacturers' assertion of "confidentiality" under the statute; and (iii) drug "manufacturers' 340B ceiling price calculations" are neither reported to nor "verified" by HHS. (*Id.*)

### E. The Secretary Has Not Enforced §340B Contracts

As summarized in the Complaint (ER 28-30), an October 2005 OIG report also concluded that the agency "does not have the necessary legislative, regulatory, or contractual authority to effectively oversee the 340B Program." (ER 419) In a May 2006 OIG report auditing AMP determinations, significant errors were found in §340B price calculations:

> In our review of the 340B program, we found two primary issues that have implications for the use of AMP as the basis of Medicaid reimbursement: the timely submission of AMP data by manufacturers and the accuracy of reported AMP data.

(ER 456) The Complaint further alleges that covered entities cannot verify the prices they are charged because Drugmakers refuse to disclose their pricing data, knowing the government cannot "impose consequences for violation[s]." (ER 28-30¶¶47-53) The OIG's 2005 investigation confirmed this allegation. (ER 418-420)

The OIG noted that §340B allows the Secretary to terminate manufacturers from the Medicaid and

§340B programs, but that such a severe sanction would be counter-productive because it would reduce "access to medications for millions of Medicaid and 340B beneficiaries." (ER 419) The OIG also found that the agency "does not verify the official Government 340B ceiling prices against manufacturers' 340B ceiling prices [charged to covered entities] to detect discrepancies. Manufacturers must calculate their ceiling prices to participate in the 340B program, but they are not required to report their final ceiling prices to [the agency]." (ER 418) The OIG stated:

> [The agency] does not check and thus is unable to detect whether manufacturers perform the calculation properly and whether entities are paying at the correct ceiling price.

(ER 419)

In a September 1, 2005 Senate Finance Committee letter to the Secretary, Senator Grassley expressed concern over OIG's findings that the agency had no access to Drugmakers' pricing data to even attempt to ensure compliance. (ER 172) Senator Grassley concluded there were "systemic problems" in the §340B program that the Secretary should address. (ER 173)

Although the Contract provides for an elective administrative "dispute resolution process" to require a manufacturer to reimburse covered entities "for discounts withheld" (ER 55), the process the Secretary has never initiated that process, and does not have the resources to do so. (ER 28-29¶¶50-52; 419; *see* ER 25¶35) Senator Grassley's letter states that: "According to the OIG, no Secretary has ever in-

itiated the dispute resolution process." (ER 173) Moreover, the Contract itself expressly provides that the elective dispute process does not preclude "exercising such other remedies as may be available by law." (ER 56(e)) The Secretary has unequivocally stated: "Covered entities . . . are not required to enter [its] informal process for resolution of disputes regarding section 340B," before "resorting to other remedies" available by law. 61 Fed. Reg. at 65411-12.

The government's *amicus* brief reveals why covered entities like respondents' have been forced to resort to suit against the Drugmakers. The government states that "if a [§]340B entity believes it is being overcharged, it can ask the manufacturer to participate in informal dispute resolution" – but it acknowledges "[n]o party is required to enter dispute resolution." (U.S. Br. at 8) The government admits that in a "not well-publicized" manner, the agency "sometimes fields calls from covered entities asking if they were overcharged for a specific drug," and "will give the entity a yes or no answer" but "[b]ecause of confidentiality" afforded the Drugmakers, "will not give the entity additional information." (*Id.*) Thus, the government's brief confirms the OIG finding of inadequate government capacity and authority to enforce §340B.

### F. After the District Court Dismissed Respondent's Contract Claim, the Court of Appeals Reversed and Held that the County Could Sue the Drugmakers as Intended Direct Beneficiaries of the Contract

The County initially sued ten major Drugmakers in state court under state law for overcharging the County's "covered entity" public health facilities for

drugs. After Drugmakers removed the action to federal court (ER 635: Doc. 1),[5] the County filed the Complaint, alleging various claims, including a claim for breach of contract. (ER 12-48)

The Complaint alleges that many of Santa Clara's medical facilities are §340B covered entities that provide health care, including prescription and over-the-counter drugs, to indigent patients covered by Medicaid. (ER 13-18¶¶1-2, 10-13) Like all California counties, Santa Clara is required to provide health-care as a "'provider of last resort'" to residents who are not able to have their basic healthcare needs met elsewhere. Cal. Welf. & Inst. Code §17000. (ER 18¶13) In support of the contract claim, the Complaint alleges that the ten Drugmakers entered into contracts with the Secretary under which they each agreed to sell drugs to §340B covered entities at discount prices, and which they each breached by charging more than the ceiling price prescribed by the Contracts and mandated by the federal statute. (ER 23-26¶¶31-45; 40-41¶¶101-104)

The district court granted Drugmakers' motion to dismiss the Complaint, concluding that Santa Clara was not entitled to sue as a third-party beneficiary of the Drugmakers' contracts with the Secretary. (Docs. 196, 212) The district court reasoned that entities may sue for breach of a contract to which they are not a party if two criteria are met: "(1) the signatories intended [the entities] to benefit directly" and (2) "intended [the entities] to have the right to sue for performance." (Doc. 196:11) The court held that the first test was satisfied, ruling that the contract

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[5] "Doc." references are to Document numbers in the district court docket. No. C-05-03740-WHA (N.D. Cal.).

clearly identified "covered entities" like plaintiffs as the intended beneficiaries of its discount prices: "These provisions clearly benefited covered entities." (Doc. 196:12) The court added that the stated purpose of §340B – which commands the Secretary to enter into these contracts – suggests that "Congress intended to benefit [covered entities] directly." (Doc. 196:13) Despite ruling that plaintiffs were the intended direct beneficiaries of the contract, the court imposed a second requirement that there must be a "'clear intent'" found within the four corners of the contract giving third-parties the right to sue to enforce its provisions. (Doc. 196:11-12)

On Santa Clara's appeal from dismissal of its contract claim, the Court of Appeals reversed and held that Santa Clara's §340B "covered entities" were entitled to sue the Drugmakers as intended direct third-party beneficiaries of Drugmakers' PPA Contracts with the Secretary:

> Applying the federal common law of contracts, we hold that the covered entities are intended direct beneficiaries of these agreements and thus have the right to enforce the agreements' discount provisions against the Manufacturers and sue them for reimbursement of excess payments.

*Santa Clara v. Astra, USA, Inc.*, 540 F.3d 1094, 1098 (9th Cir. 2008) ("*Santa Clara I*"). The Court of Appeals correctly held that the district court erred in imposing a second requirement that the contract contain a specific right to sue provision. The second requirement does not apply to intended direct beneficiaries of the contract, only to members of the public who are incidental beneficiaries. *Id.*, citing *Montana v. United States*, 124 F.3d 1269, 1273-74 (Fed. Cir.

1997); *Klamath Water Users Protective Ass'n v. Patterson*, 204 F.3d 1206, 1210-12 (9th Cir. 1999). Petitioners did not seek rehearing on this issue, and the petition for certiorari does not challenge this holding.

The Court of Appeals also held that "allowing such suits under the [Contract] is consistent with Congress' intent in enacting the Section 340B program," and rejected Drugmakers' contention that permitting a contract claim created an implied private right of action under the statute. *Santa Clara I*, 540 F.3d at 1100, 1103. The Court of Appeals distinguished the cases cited by Drugmakers because in those cases the statute created an administrative remedy, thereby negating any intent to provide a private remedy. *Id.* at 1106-08.

The Court of Appeals also expressly rejected the Drugmakers' contention that their "pricing data" – used in calculating §340B ceiling prices under the contract – was confidential and could not be disclosed. *Id.* at 1099, 1105-06. The Court of Appeals reasoned that court-ordered discovery fit within the "otherwise required by law" exception to confidentiality explicitly provided for in the Contract. (ER 56 v(a)) Finally, the Court of Appeals rejected Drugmakers' assertion of primary jurisdiction as an independent ground for affirmance. The Court found that because Santa Clara's contract claim was not particularly complicated and did not challenge the agency's guidance for calculating prices under 42 U.S.C. §1396r-8, there was no need to defer to the agency. *Santa Clara I*, 540 F.3d at 1109.

Although the scope of the Contract was neither at issue nor briefed by the parties (ER 378-90; 392-94),

the Court of Appeals severely limited its effect in its 2008 decision, stating:

> The PPA [Pharmaceutical Pricing Agreement] is drafted, for instance, so that covered entities are entitled only to the average manufacturer price ["AMP"] *reported* to the Secretary; they cannot claim that the reported figure was itself somehow erroneous.

*Santa Clara I*, 540 F.3d at 1109 (emphasis in original). Neither party petitioned for rehearing.

Immediately after remand, and relying on the single sentence in the Court of Appeals' decision appearing to limit the evidence of breach of contract to the price "reported," Drugmakers moved for a protective order to preclude discovery by Santa Clara as to any data "underlying the calculation of Average Manufacturer Prices" and expanded this to "best-price" data. (ER 5, 15, 262-63) The district court reluctantly granted Drugmakers' motion for protective order, stating that but for the sentence in the Court of Appeals' decision, it "would be inclined" to rule for the plaintiff to allow discovery to enable Santa Clara to challenge the price calculated. (ER 7)

The district court certified (ER 10-11) and the Court of Appeals accepted an interlocutory appeal under 28 U.S.C. §1292(b). (Doc. 310) After full briefing by the parties, the Court of Appeals requested an *amicus* brief from the government on the issue of primary jurisdiction. The petition fails to mention that in its *amicus* brief, the government agreed with respondents that the Drugmakers are not free to calculate ceiling prices using "reported AMP and Best Price data" but must use and report "accurate [pricing] data." (U.S. Br. at 9-11 & n.11)

The government also acknowledged that the Court of Appeals "should refrain from invoking primary jurisdiction now." (*Id.* at 12-13) The government explained that "if any overcharging resulted from purely mechanical errors, or certain obvious and intentional fraud, the issues would not be sufficiently complex to require referral to HHS." (*Id.*) Thus, the government agreed that if discovery revealed obvious and intentional overcharges, as the County alleged, the statutory scheme and the Secretary's enforcement authority would not be implicated, and "primary jurisdiction need not be invoked" because "[n]o special agency expertise is implicated by such straightforward claims." (*Id.* at 13)

The Court of Appeals accepted the government's submission and did not invoke the agency's primary jurisdiction. *Santa Clara II*, 588 F.3d at 1250 & n.19. The Court of Appeals vacated its initial decision and reissued it allowing the County to sue on the Contract without the sentence limiting suit to prices *reported*. *Id.* at 1252.

## REASONS FOR DENYING PETITION

This petition arises from the Court of Appeals' reissuance of a 2008 decision in which the panel previously had held that respondents, as intended direct third-party beneficiaries of the contract, can enforce the petitioning manufacturers' contractual obligation not to charge 340B entities more than the ceiling price for each drug. The decision from which petitioners now seek certiorari was modified only to clarify that the contractual obligation itself is not limited, as the manufacturers had argued, to charging 340B entities the ceiling prices manufacturers *actually reported* to the government. Rather, as the

government's *amicus* brief to the Court of Appeals explained, "manufacturers must *compute* ceiling prices *using* only *accurately reported values*." (U.S. Br. at 11)

The effect of the new panel decision, after the district court certified an appeal from a protective order, is to permit Santa Clara to obtain discovery of the manufacturers' actual pricing conduct. Notably, petitioners only elected to seek certiorari after the Ninth Circuit reissued its opinion.

Petitioners' legal theory erroneously conflates distinct bodies of law to create the appearance of a conflict in the lower courts. Likewise, their assertion of burden provides no valid basis for certiorari; it merely reflects petitioners' attempt to avoid exposure to liability for overcharging safety net healthcare providers.

## I. THE ASSERTED CONFLICT AMONG THE CIRCUITS DOES NOT EXIST

As the district court and Court of Appeals proceedings make clear, respondent seeks recovery for breach of contract. (2006 ER 45-49)[6] There is no split of authority on the basic contract principles involved in resolving third-party rights – nor do petitioners assert any such split.

The Court of Appeals' analysis is based entirely on "general principles for interpreting contracts," and grounded in application of the rule concerning third-party beneficiary rights in the Restatement (Second) of Contracts. *Santa Clara II*, 588 F.3d at 1244-45

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[6] All references to "2006 ER" and "2006 SER" refer to the Excerpts of Record and Supplemental Excerpts of Record filed in the first appeal in this case, Ninth Cir. 06-16471.

("'[A] third party who is an intended beneficiary of a contract may sue to enforce the contract or to obtain an appropriate remedy for breach.'"). That approach follows longstanding precedent from this Court, which has drawn on basic contract principals to resolve questions of third-party rights. *Robins Dry Dock*, 275 U.S. at 308-09.

In an attempt to recharacterize plaintiffs' claim, Drugmakers now seek to resurrect a strawman-theory that any challenge under the contract is effectively a challenge under the statute itself and somehow an impermissible attempt to establish a private right of action under the statute. (Pet. 2-3) Petitioners' attempted recharacterization mistakenly conflates implied statutory rights of action with respondents' suit for breach of the contract between Drugmakers and the Secretary for respondents' direct benefit. These are discrete claims. *Jackson Transit*, 457 U.S. at 22, 30. Under Federal Rules of Civil Procedure 12(b)(6), the claim alleged must be construed in plaintiffs' favor; Drugmakers are not free to recharacterize it. *Swierkiewicz v. Sorema, N.A.*, 534 U.S. 506, 512-14 (2002). Indeed, the district court recognized that plaintiffs advanced a federal common law contract claim, and did not address Drugmakers' implied statutory right-of-action theory. (2006 ER 45-49)[7]

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[7] Moreover, petitioners' contention that the contract claim must be viewed as an implied statutory private right claim was belated even at its inception. Drugmakers did not raise this theory in their motion to dismiss, but only for the first time in their district court reply and then only in a perfunctory one-line parenthetical to a case citation in support of their main contention that the contract contained no specific intent-to-sue. (2006 SER 118-19, 127-28) Because it was raised in reply, plaintiffs had no chance to address it in their papers (2006 SER

Petitioners rely on cases from the Second, Sixth and Tenth Circuits in an attempt to construct a circuit split. But the asserted conflict does not exist. As discussed below, the Second, Sixth and Tenth Circuit cases cited by Drugmakers simply applied settled law to preclude private suits because the relevant *statute provided a mandatory administrative remedy*. Here, §340B establishes no remedy to covered entities apart from the contract itself. There is no circuit conflict on this principle – just different results for different types of statutes. Indeed, as discussed below, none of the five circuit cases petitioners cite for the supposed contrary view were implied private statutory actions; instead they turned on determinations that plaintiffs were *incidental* third-party beneficiaries, rather than intended, direct beneficiaries of the contract, as respondents undisputedly are here.

### A. Petitioners Mistakenly Conflate Asserted Implied Statutory Private Right of Action Cases with the Contract Claim in This Case

Petitioners' purported implied right of action cases are inapposite and create no conflict. Each of them turns on the existence of a statute-mandated administrative remedy. No such remedy is provided by §340B.

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122-24), and the district court did not address it either. (2006 ER 45-48) The Court of Appeals nevertheless rejected the contention on the merits when Drugmakers raised it as an alternative ground on appeal. *Santa Clara II*, 588 F.3d at 1249-51. But the Court of Appeals' principal holding was that, as intended direct third-party beneficiaries, respondents were entitled to sue under the Contract. *Id.* at 1243-49.

In the Second Circuit case cited by petitioners, a federal statute provided that prevailing wages under city construction contracts would be "'predetermined by the Secretary of Labor,'" and provided an administrative remedy for violations. *Grochowski v. Phoenix Constr.*, 318 F.3d 80, 83 (2d Cir. 2003). Based on those provisions, the Second Circuit held that it would be "'inconsistent with'" and "'would interfere with the implementation of'" the statute, the Davis-Bacon Act, to allow a private state contract suit. *Id.* at 85-86 (concluding "plaintiff's state-law claims are indirect attempts at privately enforcing the prevailing wage schedule contained in the [statute]"). *Grochowski* is clearly inapposite. It is premised on the "'elemental canon' of statutory construction that where a statute expressly provides an exclusive remedy, 'courts must be especially reluctant to provide additional remedies.'" *Id.* at 85, quoting *Karahalios v. Nat'l Fed'n of Fed. Employees, Local 1263*, 489 U.S. 527, 533 (1989). Here, §256b does not "expressly provide" any remedies to covered entities. Unlike the Davis-Bacon Act, §256b is silent about the agency's power to promulgate regulations against manufacturers with the force of law. Unlike *Grochowski*, the private action here is consistent with the statutory scheme which created the contract. The statute provides no other remedy that would preclude suit on the contract. The Court of Appeals correctly so ruled. *Santa Clara II*, 588 F.3d at 1249-51.

Similarly, the Sixth Circuit case petitioners cite involved a discharged employee who claimed he was a handicapped individual entitled to bring a cause of action under the Vocational Rehabilitation Act. *Hoopes v. Equifax, Inc.*, 611 F.2d 134 (6th Cir. 1979). The court's entire analysis appeared in a single sen-

tence which highlights the difference here: "Even if appellant is a handicapped person under the Vocational Rehabilitation Act of 1973, 29 U.S.C. §793, *that statute provides for an administrative remedy* through the Department of Labor and does not authorize a private cause of action in the courts." *Hoopes*, 611 F.2d at 135.

Likewise, in the Tenth Circuit case, arising under the same statute, 29 U.S.C. §793, the Court of Appeals declined to allow a contract claim precisely because "the comprehensive remedial scheme provided in the statute dictates against implying another remedy" for breach of any government contract employing handicapped individuals. *Hodges v. Atchison, T & S.F.R. Co.*, 728 F.2d 414, 416 (10th Cir. 1984). In stark contrast, there is no mandatory administrative remedy for "covered entities" in this case.

The crucial omission in petitioners' analysis of their asserted circuit split is that this case involves a contract for the *direct benefit* of respondents and *no remedial scheme*, while petitioners' cases each involved statutes that created another express administrative remedy. *Hoopes*, 611 F.2d at 135 (the statute "provides for an administrative remedy through that Department of Labor"); *Hodges*, 728 F.2d at 415-16 (statutes provided for an administrative remedy or arbitration – not a private action); *Grochowski*, 318 F.3d at 85 (the statute created a mandatory administrative remedy). Because a private breach of contract action was found inconsistent in each case with Congress' creation of an express alternative remedy, no contract claim was permitted. *See Santa Clara II*, 588 F.3d at 1250-51 (analyzing *Grochowski* as a case involving statutory abrogation of state law claims).

Here, however the statute creates the contract for respondents' direct benefit and provides no alternative remedy. Instead, the PPA provides for an "elective dispute resolution process" that the Secretary has discretion to initiate (ER 55), but the contract explicitly states that the elective process does not "preclude" resort to "such other remedies as may be available by law." (ER 56) In interpreting §340B and the 340B Contract, the Secretary unambiguously stated that: "No manufacturer or covered entity is required to avail itself of this [agency dispute resolution] process before resorting to other available measures." 61 Fed. Reg. at 65411. Thus, as the agency itself interprets §340B, Congress did not intend to place jurisdiction over enforcement of §340B ceiling prices either preliminarily or exclusively within the agency. The agency's interpretation of the statute is entitled to deference. *Chevron, USA, Inc. v. NRDC*, 467 U.S. 837, 842 (1984). The 340B Contract expressly contemplates suits for breach of contract. The Court of Appeals correctly so held, and the petition does not contest that holding.

### B. The Five Cases Petitioners Cite as Creating a Circuit Split Were Not Implied Statutory Actions, but Third-Party Contract Cases Involving Incidental, Not Intended Beneficiaries

Contrary to petitioners' description, none of the five decisions purportedly creating a conflict with the Second, Sixth or Tenth Circuits is an implied right of action case. Rather, they all involve alleged contract claims. In all five cases, the courts recognized that a third-party beneficiary could sue for breach of contract if it were an intended direct beneficiary, but

concluded the plaintiffs were only incidental beneficiaries, not intended direct beneficiaries.

In *Falzarano v. United States*, 607 F.2d 506 (1st Cir. 1979), the court held that plaintiffs were "merely incidental beneficiaries," not "intended beneficiaries," and that, under the statute, "[a]uthority is given to the Secretary to seek enforcement if necessary." *Id.* at 510-11. Likewise, in *Perry v. Hous. Auth. of Charleston*, 664 F.2d 1210 (4th Cir. 1981), the court held that tenant plaintiffs were "incidental beneficiaries" and not direct beneficiaries, and as such had no third-party right under contract between their landlord, the housing authority, and the federal agency. *Id.* at 1218. Similarly, in *Nguyen v. United States Catholic Conference*, 719 F.2d 52 (3d Cir. 1983), the court held that refugees "could not be considered third-party beneficiaries" of contracts between the Catholic church *and* the government. *Id.* at 56.

In *Dewakuku v. Martinez*, 271 F.3d 1031 (Fed. Cir. 2001), contrary to petitioner's assertion that the court "entertained a third-party beneficiary common law claim for breach of contract" (Pet. 16), the Federal Circuit found that because the contract expressly provided there were "no third party contract rights conferred," plaintiff was "not an intended third party beneficiary" who could enforce a contract between the government and the Indian public housing authority. *Id.* at 1040-42.

In *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474 (7th Cir. 1985), the only case previously cited by petitioners, the court held that an employee of a government contractor was only an incidental beneficiary, not an intended "direct" beneficiary of the contract between his employer and the government, and also held the statutory grant of an exclusive

administrative remedy precluded a right of action. *Id.* at 1477-81. Here, the Ninth Circuit found, under the precise terms of the Contract that respondents were the intended direct beneficiaries of the Contract, and that §340B provided no remedy to respondents other than the Contract. *Id.*

In sum, the Court of Appeals' decision does not "deepen[] an existing 5-3 circuit" split. (Pet. 2, 12) There is no split – just two discrete lines of settled authority. Indeed, for the very obvious reason that there is no conflict, petitioners have never even mentioned the Sixth and Tenth Circuit cases they now cite in the petition during the entire five years of this litigation, and petitioners have never before cited the cases from four of the five other circuits that supposedly are in conflict.

### C. Neither §340B Nor This Court's Implied Right of Action Jurisprudence Displaces Respondent Covered Entities' Right as Intended Direct Beneficiaries to Sue for Breach of Contract

Contrary to the petition, the County's contract claim is not displaced by the statute. Section 340B neither precludes a private right of action expressly, nor does so implicitly by creating other remedies. 42 U.S.C. §256b. The statute simply mandates a contract and establishes the principal obligation to be included in the contract – drug manufacturers must charge covered entities like respondent's medical facilities no more than a ceiling price according to the formula set forth in the statute. *Id.* Respondent sues to enforce the contract.

While the *contract* creates an administrative dispute resolution process, that process is explicitly

"elective" (ER 55, §IV(a)) and non-exclusive, allowing "such other remedies as may be available by law." (2006 ER 94) Apart from being optional, the administrative process is concededly ineffective and unused. The department does not have the resources or authority to provide a remedy or to provide effective oversight. (ER 418-20) As the Inspector General found, "no Secretary has ever initiated the dispute resolution process." (ER 173)

Despite years of criticism by the Inspector General, including reports finding millions of dollars in overcharges, and rebuke from Congress, the Secretary has not resolved the issues causing overcharges and lacks the resources to do so. As the Inspector General found: "HRSA does not have the necessary legislative, regulatory, or contractual authority to effectively oversee the 340B program" or to "enforce the consequences for violations as stated in HRSA's [Contract]." (ER 419-20)

None of the principal cases from this Court cited by petitioners as precluding an implied statutory private right of action involved a contract claim arising from a government contract created by statute to implement uniquely federal interests. *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001) (disparate impact discrimination claim); *Virginia Bankshares v. Sandberg*, 501 U.S. 1083, 1102 (1991) (securities fraud claim); *Wheeldin v. Wheeler*, 373 U.S. 647, 651 (1963) (improper issuance of federal subpoena). Petitioners do not suggest otherwise. (Pet. 4, 29-30)

Petitioners cite *United States v. Erika, Inc.*, 456 U.S. 201 (1982), as their lone example of this Court's refusal to find an implied statutory private right of action involving a breach of contract. (Pet. 29-30) But the Medicare statute at issue in *Erika* is very

different from §340B and that difference supports the Court of Appeals' conclusion here that Congress did not intend to displace an intended direct beneficiary breach of contract claim to enforce the uniform contract created by §340B. The Medicare statute provided an elaborate multi-tiered agency review procedure, but omitted any procedure for judicial review of the insurance carrier's determination of health benefit claims under the statute. *Erika*, 456 U.S. at 202-06. The plaintiff in *Erika* filed suit against the government, not against the insurance carrier who refused payment, and sought recovery under the Social Security Act and applicable regulations. *Id.* at 205 & n.4. This Court found the administrative remedies provided by the statute, along with the absence of any provision for judicial review, demonstrated that Congress intended to foreclose judicial review of the agency's action by the Court of Claims under the Tucker Act. (28 U.S.C. §1491). *Id.* at 206-08.

In light of the statute-mandated administrative scheme in *Erika*, this Court also addressed plaintiff's alternative contract claim against the government, concluding that it too was precluded because the contract was subject to the statute's mandatory administrative review procedure and the statute's preclusion of judicial review. *Id.* at 211 n.14. There is no such administrative remedy or judicial preclusion in §340B. In fact, §340B only directs the Secretary to adopt procedures to ensure that covered entities comply with the program. 42 U.S.C. §256b(a)(5). And, both the §340B Contract (ER 56) and the Secretary's regulations explicitly state that "[c]overed entities . . . are not required to enter [the] informal process for resolution of disputes regarding section 340B" before "resorting to other remedies" available

by law. 61 Fed. Reg. at 65411-12. Thus, the reasoning of *Erika* supports appropriate third-party enforcement of federal contracts, irrespective of any separate implied statutory right of action.

Indeed, *Erika* confirms that there is no unresolved split in the circuits. Rather, to the extent the Second Circuit's decision in *Grochowski* conflicts with the decision below in this case, this Court's analysis in *Erika* demonstrates that the Second Circuit's reasoning was defective. It should have conducted the sort of preemption or displacement analysis modeled in *Erika*, called for by Judge Lynch in dissent in *Grochowski*, and conducted by the Court of Appeals in this case.

In sum, certiorari is unwarranted here because this is a contract claim – not an implied private statutory claim. Not only is there no conflict among the circuits, but as discussed next, petitioners do not even challenge the Court of Appeals' principal holding.

## II. PETITIONERS DO NOT CHALLENGE THE COURT OF APPEALS' HOLDING THAT RESPONDENTS ARE INTENDED DIRECT THIRD-PARTY BENEFICIARIES OF THE PHARMACEUTICAL PRICING AGREEMENTS

Consistent with this Court's precedents and the Restatement, the Court of Appeals held that when the contract reflects the "express or implied" intent of the signatories to the contract to benefit third-parties directly, they have the right to sue as the *direct* "intended beneficiaries" of the contract. *Santa Clara II*, 588 F.3d at 1244-46; citing *Klamath*, 204 F.3d at 1210-11; Restatement (Second) of Contracts §304

(1981) ("A promise in a contract creates a duty in the promisor to any intended beneficiary to perform the promise, and the intended beneficiary may enforce the duty."); *see Robins Drydock*, 275 U.S. at 307 (same).

The Court of Appeals correctly rejected the district court's additional requirement that the contract contain a specific right to sue provision. Such a provision is required only when members of the public seek redress as *indirect* "incidental beneficiaries" – a situation not remotely present here. The petition does not contest this holding by the Court of Appeals, because Drugmakers know it is correct.

The notion of a two-part test for a third-party's rights to enforce a government contract appears to originate from the Claims Court decision in *Baudier Marin Elecs., Sales and Serv. Inc. v. United States*, 6 Cl. Ct. 246, 249 (1984). In subsequent cases, however, the Court of Federal Claims reconsidered the two-part test and concluded that there was no basis for the second requirement when the party seeking redress was the intended direct beneficiary of the contract. *Schuerman v. United States*, 30 Fed. Cl. 420, 428-33 (1994). *Schuerman* held the second requirement is superfluous when the third-party is an intended direct beneficiary. *Id.* at 432-33.

In *Montana*, 124 F.3d at 1273, the Federal Circuit agreed with *Schuerman* and specifically rejected the contention that the contract must contain an explicit right-to-sue provision in order for a third-party to enforce a government contract. *Montana*, 124 F.3d at 1273; *Glass v. United States*, 258 F.3d 1349, 1354 (Fed. Cir. 2001).

The Ninth Circuit subsequently followed *Montana* and held that intended direct beneficiaries could sue. *Klamath*, 204 F.3d at 1211. The petition does not dispute that the Court of Appeals panel in this case correctly applied *Montana* and *Klamath*, consistent with this Court's decisions in *German Alliance*, 226 U.S. at 230 and *Robins Drydock*, 275 U.S. at 307. *Santa Clara II*, 588 F.3d at 1244-46.

## III. THE COURT OF APPEALS ACCEPTED THE GOVERNMENT'S SUBMISSION THAT THE COUNTY'S SUIT CAN PROCEED WITHOUT DISRUPTING GOVERNMENT PROGRAMS OR INVOKING PRIMARY JURISDICTION

Although petitioners do not purport to challenge the lower court ruling on primary jurisdiction, their contention that allowing the case to proceed will burden them unfairly is an attempt to take another bite of that same apple. In its *amicus* brief, the government urged the Court of Appeals to "refrain from invoking [the Secretary's] primary jurisdiction now." (U.S. Br. at 9, 12-13) The government explained that "plaintiff's suit does not require" agency involvement if discovery reveals that the "overcharging" by Drugmakers in breach of the pharmaceutical pricing agreements "resulted from purely mechanical errors, or certain obvious and intentional fraud, the issues would not be sufficiently complex to require referral to HHS." (*Id.* at 9) As the government explained "some [pricing] calculations might be so obviously incorrect that they could be spotted with relatively limited expertise." (*Id.* at 12)

Petitioners' overheated rhetoric that the Court of Appeals' decision has "dramatic and sweeping con-

sequences" and creates a private right of action under the §340B statute "out of whole cloth" (Pet. 12), is wrong both under the holding of the Court of Appeals and the government's view of this case, and therefore should be viewed with skepticism. The government recognized there was a balance to be struck, and the Court of Appeals adopted it by recognizing the contract claim and not invoking primary jurisdiction. Only the petitioning Drugmakers object, as they face the prospect of being held accountable for their conduct.

Contrary to petitioners' assertion, this suit enhances rather than disrupts enforcement of both the §340B and Medicaid programs. As detailed above, the OIG reports in the record reveal, and reported cases confirm, that typically it is the manufacturers' overstatement of BP that causes both lower Medicaid rebates to the States and overcharges to covered entities in excess of the correct ceiling price for drugs purchased under the §340B program. (ER 14-15 ¶4; ER 64-67) When the correct BP is lower than the reported BP, the 340b ceiling price decreases and Medicaid rebates increase – a win-win result for both states and covered entities. As the government has acknowledged already, this suit does not disrupt government programs or warrant invocation of the agency's primary jurisdiction. Accordingly, certiorari should be denied.

## CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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June 21, 2010

# REPLY BRIEF

No. 09-1273

IN THE

# Supreme Court of the United States

ASTRA USA, INC.; ASTRAZENECA PHARMACEUTICALS LP; AVENTIS PHARMACEUTICALS, INC.; BAYER CORP.; BRISTOL-MYERS SQUIBB CO.; PFIZER, INC.; SCHERING-PLOUGH CORP.; SMITHKLINE BEECHAM CORP.; TAP PHARMACEUTICAL PRODUCTS, INC.; WYETH, INC.; WYETH PHARMACEUTICALS, INC.; ZENECA INC.; ZLB BEHRING LLC.

Petitioners,

v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

Respondent.

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## REPLY BRIEF

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## PETITIONERS' REPLY BRIEF

Although Congress did not authorize a private right to enforce the drug pricing provisions of the 340B Act and the Medicaid Drug Rebate Program, the Ninth Circuit created such a right anyway. But only Congress can create a cause of action to enforce a statute. The Ninth Circuit's abuse of judicial power under the guise of federal common law warrants this Court's correction.

The decision also deepens a mature and intractable circuit conflict on whether a private plaintiff may sue under the common law as a third-party beneficiary of a government contract that incorporates a requirement of a federal statute, where the statute itself does not confer a private right of action. The question whether a statute may be enforced by a common law claim arises frequently and is of paramount importance. Billions of federal dollars are administered through government contracts that incorporate statutory requirements that Congress arguably enacted for the benefit of third parties. Few questions could be more worthy of this Court's attention than whether federal courts may authorize a private right of action when Congress concededly did not.

If left uncorrected, the decision would disrupt the 340B Act and Medicaid Drug Rebate Programs and would upend Congress's considered judgment to vest the Secretary of HHS with exclusive enforcement of those programs. Those programs are massive in size, scope, and technical complexity. The court of appeals' decision subjects an entire industry of drug manufacturers to an onslaught of private challenges with respect to every pricing calculation under the 340B Act for thousands of drugs worth billions of dollars. Those calculations are exceedingly

complicated and technical, and the pricing methodology requires a multitude of policy decisions that Congress intended the Secretary to make and implement on a uniform and centralized basis.

The decision below displaces the congressional framework with class action lawsuits that seek to impose massive liability and unjustified and extraordinary burdens on drug manufacturers. The court of appeals disrupted the statutory scheme without so much as remarking on the Secretary's view that a private right of action would disrupt her ability to administer the 340B Program as well as the vastly larger Medicaid Rebate Program whose drug pricing provisions are incorporated into the 340B Act. It is bad enough that the court invented a cause of action over Congress's refusal to create one. But the court did so also over the express objection of the two parties to PPAs, including the agency charged with administering the statute.

### A. The Conflict in the Circuits Warrants This Court's Review

1. There is a firmly entrenched circuit conflict on the question whether the federal common law provides a basis for a third-party beneficiary contract claim to enforce a statutory requirement embodied in a government contract when Congress has not authorized a private right of action to enforce the statute. Pet. 13-17. Respondents respond by asserting that the question whether a statute confers a private right of action is distinct from the question whether a third-party beneficiary can bring a common law claim under a contract that incorporates the statute. Br. in Opp. 21-23. That question, however, is precisely the issue over which the circuits are deeply divided.

Three circuits have rejected respondents' contention, holding that the absence of a statutory

right of action categorically precludes pleading the same right to sue under the guise of a common law contract claim. *Grochowski v. Phoenix Constr.*, 318 F.3d 80 (2d Cir. 2003); *Hodges v. Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414 (10th Cir. 1984); *Hoopes v. Equifax, Inc.*, 611 F.2d 134 (6th Cir. 1979). Thus, the Tenth Circuit held that "a third-party beneficiary" theory is "another aspect of the implied right of action argument." *Hodges*, 728 F.2d at 416. The Second Circuit likewise held that "common law claims are clearly an impermissible 'end run'" around Congress's decision not to provide for private enforcement of a statutory requirement. *Grochowski*, 318 F.3d at 86. And the Sixth Circuit in *Hoopes* similarly dismissed the common law claim because the statute at issue "does not authorize a private cause of action." 611 F.2d at 135.

Those decisions squarely conflict with the five circuits that have held that a common law contract claim may proceed notwithstanding the absence of a statutory right to sue. Pet. 16-17. Indeed, the Seventh Circuit in *D'Amato v. Wisconsin Gas Co.*, 760 F.2d 1474, 1478 n.4 (1985), explicitly criticized the Sixth Circuit's decision in *Hoopes* for "failing to distinguish between [a] third-party beneficiary claim and a private cause of action."

Respondents argue that none of those decisions in the five circuits "is an implied right of action case." Br. in Opp. 26. That is incorrect. Each decision involved a purported third-party beneficiary that sought to enforce a statutory requirement embodied in a contract; each decision recognized that the statute conferred no right of action; and each decision nonetheless considered whether the plaintiff met the common law elements of a third-party beneficiary. *Dewakuku v. Martinez*, 271 F.3d 1031, 1040-42 (Fed. Cir. 2001); *D'Amato*, 760 F.2d at 1478-82; *Nguyen v. U.S. Catholic Conference*, 719 F.2d 52, 55-56 (3d Cir.

1983); *Perry v. Housing Auth. of Charleston*, 664 F.2d 1210, 1218 (4th Cir. 1981); *Falzarano v. United States*, 607 F.2d 506, 511 (1st Cir. 1979). Those decisions squarely conflict with the three circuits that categorically foreclose common law claims to enforce a statute.

Respondents similarly err in suggesting that the Second, Sixth, and Tenth Circuits precluded contract claims only because the statutes at issue contained administrative remedies. Br. in Opp. 23-25. The Second and Tenth Circuits mentioned the presence of administrative remedies only in holding that Congress declined to confer a private right of action. *Grochowski*, 318 F.3d at 85; *Hodges*, 728 F.2d at 416. The presence of administrative remedies thus was irrelevant to those courts' refusal to entertain contract claims under the common law; the absence of a private right of action alone was dispositive. *Grochowski*, 318 F.3d at 86; *Hodges*, 728 F.2d at 416; *see* Pet. 19-20. Respondents thus seriously err in relying on the absence of administrative remedies under the 340B Act. Indeed, that absence makes the court of appeals' invention of a damages action all the more egregious because Congress plainly foreclosed *all* private remedies.

In any event, respondents are mistaken in limiting the Ninth Circuit's decision to statutes that lack administrative remedies. The court indicated that the common law provides a claim whenever one would benefit the plaintiff in light of the overall purposes of the statute. The court observed that a plaintiff's "right to sue inheres in one's status as an intended beneficiary," Pet. App. 39a, and further stated that "[f]ederal common law contract remedies are one way of ensuring that drug companies comply with their obligations under the program and provide [the] discounts" required by the statute, *id.* at 55a.

2. Respondents argue that, under common law contract principles, 340B entities are third-party beneficiaries under the PPAs between the Secretary and the pharmaceutical companies. Br. in Opp. 21, 25-26, 28, 31-33. That conclusion only highlights that the conflict in the circuits is squarely presented here.

Respondents' presumed status as third-party beneficiaries under common law principles is controlling in the five circuits that allow common law claims to enforce statutory requirements. But that status is irrelevant in the three circuits that categorically preclude such claims. The issue that has divided the circuits is therefore dispositive in this case, and only this Court can resolve the deep division among the courts of appeals.

3. This case is an ideal vehicle to resolve an issue of immense importance that has deeply and long divided the courts of appeals. As respondents observe, none of the circuits that have considered a federal common law claim have held that the plaintiff met the common law elements. Br. in Opp. 26-27. That is hardly surprising. Where Congress has not conferred a private right of action, a plaintiff faces an uphill battle in showing that the contracting parties intended to create a private right of action despite Congress's contrary judgment. *See* Chamber of Commerce Am. Br. 6.

Yet here the Ninth Circuit affirmatively created a cause of action that Congress itself declined to authorize. Pet. App. 36a. This case demonstrates how far from the mainstream the Ninth Circuit has strayed and underscores the need for the Court to resolve the split of authority over the question of whether federal courts may recognize common law claims to enforce a statute.

4. Respondents make no attempt to dispute that the question presented is of recurring importance and affects a wide swath of federal programs. In the health care field alone, numerous statutes are implemented through contracts that are similar to PPAs and drug rebate agreements. Pet. 19. Moreover, U.S. companies annually enter into billions of dollars worth of contracts that incorporate obligations set forth by statutes, executive orders, and regulations. Chamber of Commerce Am. Br. 14-15.

The Ninth Circuit's decision covers the largest population of any circuit. *See* U.S. Census Bureau, *Statistical Abstract of the United States* (2010), Table 12 (60 million persons). If not immediately corrected by this Court, the court of appeals' decision opens the door for countless "intended beneficiaries" of federal programs administered by contract to sue to enforce statutory requirements that Congress never intended to subject to private enforcement. And the mere presence of the conflict continues to generate litigation, uncertainty, and disruption to federal programs administered though contracts. Pet. 21-24; Chamber of Commerce Am. Br. 12-16.

### B. The Ninth Circuit's Decision Disrupts the 340B and Medicaid Drug Rebate Programs

1. Respondents do not dispute that the Ninth Circuit's decision has the immediate impact of permitting thousands of 340B entities to bring private actions for damages. Pet. 21-22. Respondents also do not dispute that, because drug manufacturers' drug pricing obligations under the 340B Program are borrowed from the Medicaid Drug Rebate Program, their suit calls into question the same pricing decisions under the rebate program. Pet. 22-23.

The impact of the Ninth Circuit's decision on both programs is staggering both in size and scope. Total Medicaid drug rebates to States and 340B discounts to covered entities approach $10 billion *annually*. PhRMA Am. Br. 16 & n.4; Pet. 21-22. Drug manufacturers must, monthly and quarterly, calculate and report AMP for over 25,000 products, and manufacturers must quarterly calculate and report BP for more than 6,300 drug products. PhRMA Am. Br. 16. Those calculations are not dictated by simple mathematical formulas. Quite to the contrary, a variety of complex and technical issues of pricing methodology must be resolved before manufacturers can calculate and report AMP and BP to the Secretary, and the Secretary in turn has given drug manufacturers considerable discretion to resolve open questions of pricing methodology. Pet. 24-25; PhRMA Am. Br. 13-20.

Given that Congress concededly conferred no private right of enforcement, the Ninth Circuit's recognition of a right to sue an entire industry warrants this Court's review. Given the sheer size, scope, and complexity of the 340B Program and the Medicaid Rebate Program, the Ninth Circuit should not have the last word on whether drug manufacturers may be exposed to massive unanticipated claims and varying and possibly conflicting obligations as courts sort through what is the "correct" AMP or BP.

2. The Ninth Circuit did not address the government's view that it "never imagined that a 340B entity could bring a third-party beneficiary lawsuit" and that such suits confer "rights never intended by the PPA signatories." Brief of the United States of America as Amicus Curiae in Support of the Judgment Below, *County of Santa Clara v. AstraZeneca Pharm. LP*, No. 09-15246, 2009 WL 4089524, at *9, *12 (9th Cir. Oct. 27, 2009)

("Gov't Br."); Pet. 24-26, 33. The court thus ignored the Secretary's judgment that private suits would "threaten the orderly operation of *both*" the Medicaid drug rebate and 340B programs by "undermin[ing]" HHS's supervision of both programs. Gov't Br., 2009 WL 4089524, at *9, *11. The Ninth Circuit's disregard of the Secretary's view warrants this Court's correction.

Respondents remark that their suit produces a "win-win" under the Medicaid drug rebate and 340B programs because a lower BP generally benefits States as well as 340B entities. Br. in Opp. 34. That observation ignores and does not refute the government's view that States and 340B entities have conflicting incentives with respect to *AMP*. Gov't Br., 2009 WL 4089524, at *15; *see* Pet. 25-26; PhRMA Am. Br. 21. Thus, manufacturers are placed in the untenable position of being exposed to conflicting AMP obligations depending on the identity of the plaintiff. Even with respect to BP, private suits expose manufacturers to case-by-case determinations of the correct BP, where Congress left that determination exclusively to the Secretary to make on a uniform, nationwide basis.

3. Respondents rely on the government's view below that this case would not implicate the Secretary's primary jurisdiction under certain circumstances. Br. in Opp. 20, 33-34. The government advised the Ninth Circuit that respondents, in theory, could limit their suit to allegations of mechanical error or outright fraud, without contesting the drug manufacturers' underlying AMP and BP pricing methodology and calculations, *i.e.*, those areas in which private suits would seriously interfere with HHS's enforcement of both programs. Gov't Br., 2009 WL 4089524, at *13-*14.

After the government filed its brief, however, the Ninth Circuit's superseding opinion deleted the prior language that suggested the suit was limited to reported prices. Pet 12; *see* Pet. App. 65a-66a. On remand respondents challenged and sought massive discovery with respect to well over a hundred million records relating to intricate and confidential pricing methodology, thus implicating the very concerns leading the Secretary to conclude that private suits are incompatible with congressional intent and her exclusive enforcement of both programs. Pet. 23-24.

### C. The Ninth Circuit's Decision Is Manifestly Wrong

1. Respondents concede that the 340B Act contains no private right of action and confers no private remedies to enforce the drug pricing requirements. Br. in Opp. 3-4. That should have been the end of the matter. This Court has long since abandoned a general federal common law, and our constitutional structure permits only Congress to permit private enforcement of legislative enactments. Pet. 26-33. The Ninth Circuit's holding flagrantly disregards this Court's recent implied right of action jurisprudence, Pet. 31-32, and turns that jurisprudence on its head by holding that the federal common law of contracts "ordinarily" provides a cause of action that Congress must "*abrogate*." Pet. App. 24a n.16 (emphasis added); *accord* Br. in Opp. 28 ("[T]he County's contract claim is not displaced by the statute.").

A common law claim renders the absence of an implied right of action meaningless since the substantive right to enforce the requirement is the same under either doctrine. Respondents do not

argue to the contrary. This Court's Spending Clause jurisprudence moreover requires that Congress speak with a clear voice before authorizing a private suit against a party that "contracts" with the government under Spending Clause legislation. Pet. 32-33. *A fortiori*, courts lack the power on their own to impose unanticipated liabilities on contractors.

This Court's decision in *United States v. Erika, Inc.*, 456 U.S. 201, 206-211 (1982), rejects the notion that a plaintiff can circumvent the absence of a private right of action by alleging that it is a third-party beneficiary to a government contract. Pet. 28-30. Contrary to respondents' assertion, Br. in Opp. 29-31, *Erika*'s rejection of the contract claim was not based on the presence of administrative remedies. Rather, the Court explained that its task was "at an end" upon concluding that Congress intended to withhold a judicial remedy. 456 U.S. at 211. Indeed, because this Court's decisions squarely foreclose the holding below and because the Ninth Circuit is the only circuit court to have upheld a common law claim to enforce a statute, this Court may wish to consider summary reversal.

Respondents err in relying (Br. in Opp. 4-5) on *Jackson Transit Authority v. Local Division 1285*, 457 U.S. 15 (1982), and *Clearfield Trust Co. v. United States*, 318 U.S. 363 (1943). Those decisions addressed whether federal or state law governed a contract claim. *Cf. Boyle v. United Techs. Corp.*, 487 U.S. 500 (1988) (tort action). *Jackson Transit* also is inapposite because the plaintiff was a party to the contract, and the Court held that Congress intended that the contract be enforceable, albeit under state

law. 457 U.S. at 21 ("[T]he precise question before us is whether the union's contract actions are federal causes of action, not whether the union can bring suit at all to enforce its contracts."). Similarly, *congressional intent* controls the scope of the cause of action. *Id.*; *see also Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 694-695 (2006). No decision of this Court supports the proposition that where Congress declines to create a cause of action, a court may create one anyway.[1]

## CONCLUSION

For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted or the decision summarily reversed.

Respectfully submitted,

---

[1] Respondents cite inapposite decisions that do not involve a federal statute. Br. in Opp. 4 (citing *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303 (1927), and *German Alliance Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220 (1912)), and decisions involving suits by or against the United States, *id.* at 5 (citing *United States v. Little Lake Misere Land Co.*, 412 U.S. 580 (1973), and *United States v. Kimbell Foods, Inc.*, 440 U.S. 715 (1979)).

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JULY 6, 2010

# AMICUS CURIAE BRIEF

Supreme Court U.S.
MAY 20 2010
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No. 09-1273

# In the Supreme Court of the United States

ASTRA USA, INC., ET AL., PETITIONERS

*v.*

COUNTY OF SANTA CLARA

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT*

## BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

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COUNTY OF SANTA CLARA

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT*

## BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

### INTEREST OF AMICUS CURIAE

The Chamber of Commerce of the United States of America (Chamber) is the Nation's largest federation of business companies and associations. It directly represents 300,000 members and indirectly represents the interests of over 3 million business, trade, and professional organizations of every size, in every business sector, and from every region of the country. A central function of the Chamber is to represent the interests of its members in important matters before the courts, Congress, and the Executive Branch. To that end, it

files briefs as amicus curiae in cases that raise issues of vital concern to the Nation's business community.[1]

This case presents a simple question of exceptional importance to the Chamber's members: *viz.*, whether a private plaintiff may sue as a third-party beneficiary of a government contract that incorporates the requirements of a federal statute where the statute itself does not confer a private right of action. In the decision below, the Ninth Circuit deepened an already substantial circuit conflict by holding that a private plaintiff may be able to sue as a third-party beneficiary in such circumstances. And it went further than any other circuit had previously gone by holding that the plaintiff here was actually entitled to sue on a third-party beneficiary theory.

The Ninth Circuit's decision directly implicates the interests of the Chamber's members. Millions of American businesses annually enter into contracts with the federal government in a wide range of industries including construction, manufacturing, transportation, and utilities. Those contracts routinely require contracting parties to comply with statutory or regulatory requirements as a condition of doing business with the government. Until the decision below, no court of appeals had permitted a private plaintiff to bring suit to enforce

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[1] Pursuant to Rule 37.6, the Chamber affirms that no counsel for a party authored this brief in whole or in part; no such counsel or a party made a monetary contribution to fund its preparation or submission; and no person other than the Chamber, its members, or its counsel made such a monetary contribution. Pursuant to Rule 37.2, counsel of record received timely notice of the Chamber's intent to file this brief at least ten days before the due date. The parties have consented to the filing of this brief, and copies of their letters of consent are on file with the Clerk's Office. Counsel for the Chamber represents some of the petitioners on unrelated matters.

those requirements as a third-party beneficiary of the contract where, as is frequently the case, the plaintiff had no statutory right of action.

The practical consequences of the Ninth Circuit's decision are sweeping. If that decision is allowed to stand, companies that do business with the government will be exposed to burdensome and expensive litigation, with the possibility of significant liability and the unjustified disclosure of confidential information. The decision below will disrupt the settled expectations not only of the private sector, but also of numerous government departments and agencies that depend on the private sector to provide goods and services in a cost-effective manner—including, as in this case, goods and services that are vital to promoting the public welfare. And the decision below threatens to create a disincentive for businesses to enter into government contracts in the future—an outcome that would disserve the interests of millions of Americans whose lives are improved through public-private partnerships embodied in government contracts such as those at issue here. For the reasons stated in this brief, the Chamber respectfully urges the Court to grant review.

## SUMMARY OF ARGUMENT

Further review is warranted in this case for three principal reasons.

*First,* the Ninth Circuit's decision deepens a long-standing circuit conflict on whether a private plaintiff may sue as a third-party beneficiary of a government contract that incorporates requirements of a federal statute where the statute itself does not confer a private right of action. Six courts of appeals (including the Ninth Circuit in the decision below) have now held that a third-party beneficiary may be able to sue in such cir-

cumstances, and three courts of appeals have held to the contrary. Despite the Ninth Circuit's best efforts, those decisions cannot be reconciled, and the resulting conflict warrants this Court's intervention.

*Second*, the Ninth Circuit's decision is patently erroneous. In permitting a private plaintiff to bring suit under the guise of federal common law in order to enforce a federal statutory requirement, the Ninth Circuit flouted this Court's repeated admonitions concerning the limitations on the invocation of federal common law and on the recognition of implied rights of action. Under a proper reading of the Court's decisions, the absence of a private right of action to enforce the statutory requirements at issue should foreclose efforts to enforce those requirements through other means. This Court should grant certiorari in order to bring the Ninth Circuit's aberrant mode of analysis in line with the Court's earlier decisions.

*Third*, the Ninth Circuit's decision is extraordinarily harmful to American businesses, both in the immediate context and in many others. By using federal common law to permit a private party to bring suit, the decision below threatens to expose businesses to liability that neither they nor the federal government envisioned in entering into contractual arrangements implementing statutory requirements. And it would wreak havoc on statutory schemes (like the one at issue here) that by their terms contemplate the possibility only of government, and not of private, enforcement. The dramatic consequences of the Ninth Circuit's decision confirm the need for this Court's review.

## ARGUMENT

### A. The Decision Below Deepens A Circuit Conflict Concerning The Availability Of A Private Right Of Action Under Federal Common Law In The Absence Of A Statutory Right

1. As the petition explains (at 13-21), even before the Ninth Circuit's decision, the courts of appeals were intractably split on the question whether a private plaintiff may sue as a third-party beneficiary of a government contract that incorporates requirements of a federal statute where the statute itself does not confer a private right of action. On the one hand, three courts of appeals had held that a private plaintiff could never sue in those circumstances. See *Grochowski* v. *Phoenix Construction*, 318 F.3d 80, 86 (2d Cir. 2003); *Hoopes* v. *Equifax, Inc.*, 611 F.2d 134, 135 (6th Cir. 1979); *Hodges* v. *Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414, 416 (10th Cir. 1984). Most notably, in *Grochowski*, the Second Circuit considered third-party beneficiary claims brought by private plaintiffs on the ground that the defendants had violated the minimum-wage requirements of the Davis-Bacon Act (DBA), 40 U.S.C. 3141 *et seq.* See 318 F.3d at 83-84. The court refused to permit the claims to proceed. See *id.* at 84-86. The court reasoned that the DBA did not confer a private right of action, *id.* at 85; that the plaintiffs' third-party beneficiary claims constituted "indirect attempts at privately enforcing the prevailing wage schedules contained in the DBA," *id.* at 86; and that the claims were thus "clearly an impermissible 'end run' around the DBA," *ibid.*[2]

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[2] Numerous district courts in other circuits had reached the same conclusion. See, *e.g.*, *Rogers* v. *United States Army*, No. 06-1389, 2007 WL 1217964, at *11-*12 (S.D. Tex. Apr. 23, 2007); *Brug* v. *Na-*

On the other hand, five courts of appeals had held that a private plaintiff could sue even in the absence of a statutory right of action. See *Falzarano* v. *United States*, 607 F.2d 506, 509-511 (1st Cir. 1979); *Nguyen* v. *United States Catholic Conference*, 719 F.2d 52, 55-56 (3d Cir. 1983) (per curiam); *Perry* v. *Housing Authority*, 664 F.2d 1210, 1217-1218 (4th Cir. 1981); *D'Amato* v. *Wisconsin Gas Co.*, 760 F.2d 1474, 1477-1478 & n.3 (7th Cir. 1985); *Dewakuku* v. *Martinez*, 271 F.3d 1031, 1040 (Fed. Cir. 2001). Critically, none of those courts determined that the plaintiff at issue was actually *entitled* to sue; instead, they merely recognized the possibility that a plaintiff *could* sue on a third-party beneficiary theory in some circumstances. That is not surprising, because, as Judge Weinstein observed, "the same considerations largely determine" whether "[a] plaintiff may sue as a third-party beneficiary of the contract mandated by [a] statute" as whether "the plaintiff has [an implied] right of action under the statute." *Davis* v. *United Air Lines, Inc.*, 575 F. Supp. 677, 680 (E.D.N.Y. 1983); accord, *e.g.*, *Price* v. *Pierce*, 823 F.2d 1114, 1120 (7th Cir. 1987) (Posner, J.).

2. The Ninth Circuit's decision in this case deepens the preexisting circuit conflict. See, *e.g.*, Pet. App. 11a. Indeed, it goes even further than the other circuits that had previously held that a plaintiff could sue on a third-party beneficiary theory, by holding that respondent in this case was actually entitled to sue (on the theory that it and other covered entities were in fact intended beneficiaries of the contracts at issue). See *id.* at 11a-16a.

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*tional Coalition for the Homeless*, 45 F. Supp. 2d 33, 41 (D.D.C. 1999); *Robinson* v. *Jacksonville Shipyards, Inc.*, 760 F. Supp. 1486, 1532 (M.D. Fla. 1991).

The Ninth Circuit's decision therefore appears to be the first by a court of appeals to permit a private plaintiff to bring suit to enforce statutory requirements as a third-party beneficiary of a contract in the absence of a statutory right of action.

Even in the absence of a circuit conflict, that extraordinary outcome would warrant this Court's intervention. But there can be no doubt that a circuit conflict exists, as the Ninth Circuit's strained efforts to distinguish *Grochowski* illustrate. The Ninth Circuit contended that the "analytical underpinning" of *Grochowski* was that "additional remedies" were available under the Davis-Bacon Act (purportedly unlike the statute at issue here, Section 340B of the Public Health Service Act, 42 U.S.C. 256b). See Pet. App. 25a-26a. In *Grochowski*, however, the Second Circuit did not rely on the presence of "additional remedies" in rejecting the third-party beneficiary theory: instead, it merely noted that the Davis-Bacon Act did not confer a private right of action, 318 F.3d at 85, and then concluded that the plaintiffs' third-party beneficiary claims constituted "indirect attempts at privately enforcing" the DBA's substantive requirements, *id.* at 86. If the Ninth Circuit had applied *Grochowski*'s reasoning here, it necessarily would have held that respondent's claim was foreclosed, because respondent has conceded that Section 340B confers no private right of action. See Pet. App. 22a. As a result, the Ninth Circuit's decision cannot be reconciled either with *Grochowski* or with the decisions of other circuits rejecting the third-party beneficiary theory. The ensuing circuit conflict warrants this Court's review.

**B. The Court Of Appeals' Decision Is Erroneous**

1. The Ninth Circuit's decision to permit a private plaintiff to bring suit to enforce statutory requirements under federal common law also cannot be reconciled with this Court's decisions. As the Court has recognized, "[t]here is, of course, 'no federal general common law.'" *Texas Industries, Inc.* v. *Radcliff Materials, Inc.*, 451 U.S. 630, 640 (1981) (quoting *Erie R.R. Co.* v. *Tompkins*, 304 U.S. 64, 78 (1938)). To be sure, the Court has permitted the fashioning of federal common law in "few and restricted instances." *Atherton* v. *FDIC*, 519 U.S. 213, 225 (1997) (internal quotation marks and citation omitted). Those instances involve certain "havens of specialty," *Sosa* v. *Alvarez-Machain*, 542 U.S. 692, 726 (2004), such as international relations, see *Banco Nacional de Cuba* v. *Sabbatino*, 376 U.S. 398, 424-427 (1964), and disputes between the States, see *Illinois* v. *City of Milwaukee*, 406 U.S. 91, 103-105 (1972). And to that end, the Court has held that federal common law governs the interpretation of contracts to which the federal government is a party. See, *e.g.*, *United States* v. *Seckinger*, 397 U.S. 203, 209-210 (1970).

2. This Court, however, has never sanctioned the use of federal common law as a means to enforce requirements in federal statutes that lack a private right of action. That is for good reason, because a claim by a private plaintiff seeking to enforce a statutory requirement on a third-party beneficiary theory is simply an implied right of action by another name. Particularly in recent years, the Court has repeatedly cautioned against judicial recognition of implied rights of action. See, *e.g.*, *Gonzaga University* v. *Doe*, 536 U.S. 273, 286 (2002) (explaining that, "where the text and structure of a statute provide no indication that Congress intends to create new individual rights, there is no basis for a private

suit"); *Correctional Services Corp.* v. *Malesko*, 534 U.S. 61, 67 n.3 (2001) (warning that "we have retreated from our previous willingness to imply a cause of action where Congress has not provided one"); *Alexander* v. *Sandoval*, 532 U.S. 275, 286-287 (2001) (noting that "private rights of action to enforce federal law must be created by Congress," even if a private right of action might be "desirable * * * as a policy matter" or "compatible with the statute"). The Court has explained that "the Judiciary's recognition of an implied private right of action necessarily extends its authority to embrace a dispute Congress has not assigned it to resolve." *Stoneridge Investment Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148, 164-165 (2008) (internal quotation marks and citation omitted). And where, as here, a private right of action would coexist with an express government enforcement mechanism, the result would be particularly problematic, because it would "permit enforcement without the check imposed by prosecutorial discretion." *Sosa*, 542 U.S. at 727.

There is particular reason, moreover, not to permit a right of action to be created under the guise of federal common law. Because federal common law is "subject to the paramount authority of Congress," *Northwest Airlines, Inc.* v. *Transport Workers Union*, 451 U.S. 77, 95 (1981) (citation omitted), it is only "resorted to in absence of an applicable Act of Congress." *City of Milwaukee* v. *Illinois*, 451 U.S. 304, 314 (1981) (brackets, internal quotation marks, and citation omitted). Here, precisely such an "applicable Act of Congress" existed, in the form of Section 340B. Any private right of action to enforce the requirements of that provision must be derived by "interpret[ing] the statute Congress has passed." *Sandoval*, 532 U.S. at 286. And the conceded absence of a private right of action in Section 340B ends

the analysis, because federal common law cannot confer a right of action where the statute does not. Cf. *Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Curran*, 456 U.S. 353, 401 (1982) (Powell, J., dissenting) (noting the "fundamental legal error" of "basing a finding of an implied cause of action under a federal statute on common-law principles"). Even assuming that, as the Ninth Circuit contended, a right of action would be "wholly compatible with the [statute's] objectives," Pet. App. 26a, it would provide no basis for recognizing either an implied right of action or a right of action based on federal common law, because this Court long ago "abandoned" the notion that courts should "provide such remedies as are necessary to make effective the congressional purpose expressed by a statute." *Sandoval*, 532 U.S. at 287 (internal quotation marks and citation omitted).

The Ninth Circuit's decision is therefore flatly inconsistent with this Court's precedents concerning the limitations on the recognition of private rights of action to enforce statutory requirements. The Court should grant review to correct the Ninth Circuit's impermissibly expansive approach.

### C. The Question Presented Is An Exceptionally Important One To American Businesses And Warrants The Court's Review In This Case

If left undisturbed, the Ninth Circuit's decision will have far-reaching and profound consequences for the millions of American companies that do business with the federal government. The decision threatens not only to impose substantial costs on those companies, but to disrupt the operations of government departments and agencies and to disserve the interests of millions of Americans who benefit from public-private partnerships of the type at issue here. This case presents an ideal op-

portunity for the Court to address a question of exceptional practical, as well as legal, significance.

1. This Court has long warned of the baleful consequences of expanding private enforcement of a federal statute through judicial fiat. Where a statute does not expressly confer a right of action, the judicial recognition of such a right disrupts the expectations of would-be defendants, who are suddenly forced to grapple with "extensive discovery," "the potential for uncertainty and disruption," and other litigation-related burdens that substantially raise the "costs of doing business." *Stoneridge*, 552 U.S. at 163-164. In many cases, those burdens will be sufficiently onerous as to "allow plaintiffs with weak claims to extort settlements from innocent [defendants]." *Id.* at 163; see *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 558 (2007) (referring to litigation tactics that "take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value") (citation omitted). Where the defendant is a business, moreover, the costs of defending against such litigation will be either absorbed (and thus borne by investors and employees) or passed on to consumers. See *Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 189 (1994).

The foregoing concerns apply with even greater force where, as here, the question is whether to recognize a right of action to enforce a statutory obligation by means of a third-party contract claim. Contract law demands "certainty and predictability." *Central Bank*, 511 U.S. at 188 (citation omitted). As with any other type of contract, parties to a government contract seek to establish the full scope of their obligations and potential liabilities *ex ante*, by memorializing them in a written document that reflects the parties' mutual understanding. Cf. *Hollerbach* v. *United States*, 233 U.S. 165, 171 (1914) (noting

that "[a] government contract should be interpreted as are contracts between individuals, with a view to ascertaining the intention of the parties and to giv[ing] it effect accordingly"). The expectations of the parties would be wholly disrupted, however, if a court were to permit an alleged third-party beneficiary to bring suit—and thereby potentially to impose massive costs on one of the parties to the contract—for the purpose of enforcing an obligation in a statute that does not by its terms allow for private enforcement.

2. This case amply demonstrates the dangers of permitting suit under federal common law in the absence of an express right of action. It is undisputed that, in entering into the contracts at issue, neither petitioners nor the Department of Health and Human Services (HHS) contemplated that Section 340B entities such as respondent would be able to sue as third-party beneficiaries to enforce petitioners' statutory obligations. See Gov't C.A. Br. 21 (noting that "HHS never imagined that a [Section] 340B entity could bring a third-party beneficiary lawsuit like [respondent's]"). Nor should petitioners or HHS have had reason to expect such litigation, in light of the absence of a private right of action in Section 340B and the extensive enforcement mechanisms already at HHS's own disposal. See *id.* at 13 (describing "Congress's comprehensive administrative and enforcement scheme," including HHS's powers to terminate contracts and to exclude manufacturers from Medicaid programs, and concluding that permitting third-party claims would "undermine HHS's role").

Put simply, the Ninth Circuit's decision upends the settled expectations of both petitioners and the federal government; it disrupts the complex and carefully calibrated framework that Congress established for the administration and enforcement of the Section 340B drug-

pricing and Medicaid rebate programs; and it exposes petitioners to all of the same consequences they would have faced if the Ninth Circuit had simply recognized an implied right of action in Section 340B. In this case, moreover, those consequences are particularly acute. Petitioners face the prospect of costly and extensive discovery—all on the basis of a handful of reports (one later rescinded) by HHS's Office of the Inspector General that do not even identify any specific manufacturers. See Pet. App. 99a, 109a-110a. And the litigation in this case threatens not only to result in potentially substantial liability, but to reveal information concerning petitioners' pricing policies that both petitioners and the federal government had previously understood to be held in confidence. Those serious ramifications would give any company pause before entering into a contract with the government—an outcome that cannot be reconciled either with congressional intent in enacting the particular statute at issue or with the broader government policy favoring public-private partnerships.

3. The highly detrimental consequences of the Ninth Circuit's decision reach far beyond the immediate context of this case. The Ninth Circuit's methodology, which would permit a private plaintiff to bring suit to enforce statutory requirements as a third-party beneficiary of a contract in the absence of a statutory right of action, could apply whenever a government contract incorporates an underlying statutory or regulatory requirement. The implications of that approach confirm the need for this Court's review.

To begin with, the scope of federal contracting is enormous. One recent estimate suggests that there are more than *seven million* federal contractors. See Kevin R. Kosar, *Privatization and the Federal Government: An Introduction*, Congressional Research Service Re-

port for Congress 16 (Dec. 28, 2006) (CRS Report) <tinyurl.com/crsreport>. In 2007 alone, American companies conducted approximately $460 billion of business with the federal government—more than twice as much as a decade earlier. See Federal Procurement Data System, *Federal Procurement Report, FY 2007*, at 2 (FPDS Report) <tinyurl.com/2007fpdsreport>. Some $70 billion of those contracts involved small businesses. See *id.* at 6. Even before the most recent spasms of growth in the size of government, government contracts constituted a substantial portion of diverse sectors of the national economy, including manufacturing ($164 billion in 2007); professional, scientific, and technical services ($123 billion); construction ($31 billion); transportation ($8 billion); and utilities ($2 billion). See *id.* at 31-34. And numerous government departments and agencies enter into sizable contracts with the private sector, including the Departments of Energy ($23 billion); Health and Human Services ($14 billion); Housing and Urban Development ($12 billion); and Veterans Affairs ($12 billion). See *id.* at 10. Those numbers, moreover, do not include federal grants to state and local governments, which often in turn direct the grants to the private sector in order to "construct and repair roads, build waste treatment plants, fund community renewal efforts, and so forth." CRS Report 18 n.82.

Unsurprisingly, when companies and the government enter into contractual arrangements, companies are often required to comply with statutory or regulatory requirements as a condition of doing business with the government. To take but a few examples, the Davis-Bacon Act requires companies undertaking construction projects for the government to pay their workers according to a wage schedule set by the Department of Labor. See 40 U.S.C. 3142. The Rehabilitation Act requires

companies doing business with the government to take "affirmative action" to employ disabled individuals. See 29 U.S.C. 793. And Executive Order 11,246 requires companies doing business with the government to agree not to discriminate on the basis of race, creed, color, or national origin. See Exec. Order No. 11,246, § 202, 30 Fed. Reg. 12,320 (1965), *reprinted in* 42 U.S.C. 2000e note.

None of the foregoing provisions confers an express right of action to enforce its requirements; the same is true for the vast majority of other statutes applicable to government contractors. The Ninth Circuit's decision, however, would replace the traditional understanding that the absence of a private right of action forecloses suit with an open-ended approach that invites speculation as to whether a private party was an intended beneficiary of the statute or contract in question. The practical effect of such an approach would be to expose any company that has entered into a government contract incorporating an underlying statutory requirement to the potential of costly and unanticipated litigation. It would create a serious disincentive for companies to engage in business with the government going forward. And it would impose burdens on the government itself, insofar as the government would have to provide greater compensation to offset the potential costs of third-party litigation and thereby induce companies to enter into government contracts.

Perhaps the most serious of those consequences is the chilling effect the Ninth Circuit's approach promises to have on business activity between the private and public sectors. "Since its founding in 1789, the federal government has used private firms to provide goods and services." CRS Report 1; see, *e.g.*, Act of Aug. 7, 1789, § 3, 1 Stat. 54 (requiring the Secretary of the Treasury to

"provide by contracts * * * for building a lighthouse near the entrance of Chesapeake Bay"). The federal government has frequently turned to the private sector to provide goods and services to the American people in a cost-effective, high-quality, and reliable manner. Private entities now manage public schools, run prisons, oversee welfare programs, provide drug-abuse counseling, and offer employment training. See Martha Minow, *Public and Private Partnerships: Accounting for the New Religion*, 116 Harv. L. Rev. 1229, 1231-1232, 1267 (2003). And they are often integrally involved in major government policy initiatives, as illustrated by the health-care programs at issue here.

By destabilizing existing government contracts and creating disincentives for companies to enter into new ones, the Ninth Circuit's decision disrupts the public-private partnerships that have long contributed to the well-being of the country and its citizens. To be sure, it is well established that private entities that do business with the government may not act with impunity. The same statutory provisions that authorize particular government contracts, however, must also establish any available enforcement mechanisms. And it is ultimately up to the political branches to decide what enforcement mechanisms to provide and who may invoke them. It is not the role of the Judiciary to substitute its judgment for that of the political branches and to create as a matter of federal common law a right of action that does not exist as a matter of statute. The Ninth Circuit's decision to arrogate such lawmaking authority to itself is erroneous and has far-reaching implications. The Court should grant review and reverse that decision.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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# AMICUS CURIAE BRIEF

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In the
# Supreme Court of the United States

ASTRA USA, INC., ET AL.,

*Petitioners,*

v.

COUNTY OF SANTA CLARA,

*Respondent.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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May 21, 2010

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## INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. *See* http://www.phrma.org/member_company_list (listing approximately 40 members, international affiliates, and research associates). PhRMA's mission is to advocate in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines for patients by pharmaceutical and biotechnology research companies. PhRMA members invested approximately $45.8 billion in 2009 in the discovery and development of new medicines. *See* 2009 Industry Profile, *available at* http://www.phrma.org/profiles_and_reports.

PhRMA closely monitors legal issues that impact the pharmaceutical and biotechnology industries. To that end, PhRMA has frequently participated in cases before this Court. *See, e.g., Merck & Co., Inc v. Reynolds*, 130 S. Ct. __ (2010) (No. 08-905); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (No. 05-130).

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[1] Counsel of record for all parties were given timely notice of *amicus curiae*'s intention to file this brief as required by Rule 37.2(a) and have consented to its filing. Letters reflecting such consent are on file with the Clerk's Office. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund its preparation or submission. No person other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

This petition is of critical importance to the drug and biologic industries. By holding that 340B entities have a cause of action under federal common law to seek damages as third-party beneficiaries of contracts between the Department of Health and Human Services ("HHS") and drug manufacturers, the decision below exposes PhRMA members to an onslaught of litigation that they — like HHS — could not have imagined. *See* U.S. CA9 Br. 21. The 340B program and the Medicaid drug rebate program from which the 340B program borrows its pricing inputs are vast in scope and rife with technical complexity. If the decision below is left unreviewed, judicially-created damages suits will wreak havoc in this important field, undermining the uniformity and predictability that Congress sought to achieve by delegating the administration of these programs to HHS. PhRMA is filing this brief to underscore why certiorari is needed.

## INTRODUCTION AND SUMMARY OF ARGUMENT

In creating the 340B program, Congress sought to conserve federal resources and maximize healthcare coverage by allowing certain favored purchasers to buy drugs at a discount. Congress did not, however, provide a private cause of action to allow 340B entities to enforce the statute's discount pricing provisions through damages suits. That should be the end of the story. The law is now clear that unless Congress intends to create a cause of action, "a cause of action does not exist and courts may not create one." *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001).

For the Ninth Circuit, however, Congress's failure to provide a damages remedy was a point of departure. The court below viewed Congress's failure to provide a cause of action as an invitation to augment Congress's work via the federal common law. That maneuver is out of step with the entire thrust of this Court's recent jurisprudence on implied causes of action, the limited scope of federal common law, and the proper role of the Article III courts. Limits on courts' authority to infer rights of action from silent federal statutes are hardly meaningful if courts can simply retreat to federal common law to fashion the same remedy. The decision below exemplifies a view of the role of the federal courts in our system of separated powers that this Court laid to rest long ago.

The Ninth Circuit's circumvention of this Court's implied rights of action precedents is especially problematic because of the nature of the regulatory scheme at issue here. Congress implemented the 340B program using pricing metrics — "Average Manufacturer Price" ("AMP") and "Best Price" ("BP") — that it adopted unchanged from the Medicaid drug rebate program. Injecting uncertainty and potential inconsistency into the determination of those pricing metrics through judicially-created federal common law claims will undermine the orderly and reasonable administration of not only the 340B program, but also the far larger Medicaid rebate program. AMP and BP are not self-evident mechanical computations; to the contrary, the rules of their calculation in the dynamic and complex pharmaceutical marketplace require the application of thoughtful policy judgments. Congress made clear that those judgments were to be made by HHS

subject to APA review, not by the federal courts in a freewheeling exercise in federal common law. And judgments about how to determine AMP and BP necessarily must apply to both programs. A drug cannot have one AMP (or BP) for a 340B purchaser and a different amount or calculation methodology for a state Medicaid agency. Moreover, the Ninth Circuit's focus on the 340B purchasers as the intended beneficiaries ignores the interrelationship between the interests of 340B purchasers and the States: a higher AMP benefits States by raising their Medicaid rebate payments but harms 340B entities by raising the ceiling price for their purchases. HHS can make a single determination subject to review under APA principles that give appropriate deference to HHS. Private damages actions can neither yield a single determination nor provide for appropriate deference. Congress's decision to confer the administration of these programs to HHS should be respected rather than treated as an invitation for judicial creativity.

The Ninth Circuit's decision exposes drug manufacturers to the threat of lawsuits by over 14,500 340B entities, relating to thousands of drug products, challenging AMP and BP as reported to HHS in scores of months and quarters, and involving billions in purchases. All of this would be governed by the vagaries of federal common law. Neither party to the Pharmaceutical Pricing Agreements could have imagined that petitioners could face such an onslaught of burdensome and unpredictable litigation. Such litigation will harm the public interest by embroiling both Medicaid and the 340B program in confusion and uncertainty, if not outright inconsistent judicial directives. And

nothing in Congress's enactments provides any warrant for such litigation. For all these reasons, this Court should grant certiorari.

## ARGUMENT

### I. THE DECISION BELOW END-RUNS THIS COURT'S LIMITS ON IMPLIED PRIVATE RIGHTS OF ACTION.

#### A. The Ninth Circuit Fashioned A Federal Common Law Claim To Circumvent The Absence Of A Statutory Right Of Action.

The decision below is inconsistent with the entire thrust of four decades of this Court's jurisprudence concerning implied rights of action and related issues. In devising a private right of action in the *conceded absence* of a statutory right of action, the Ninth Circuit "revert[ed] in this case to the understanding of private causes of action that held sway 40 years ago." *Sandoval*, 532 U.S. at 287. It may once have been this Court's view that courts' duty was "to provide such remedies as are necessary to make effective the congressional purpose" reflected by a statute. *J.I. Case Co. v. Borak*, 377 U.S. 426, 433 (1964). But that view has long since been "abandoned." *Sandoval*, 532 U.S. at 287.

Since *Cort v. Ash*, 422 U.S. 66 (1975), this Court has consistently and with increasing vigor rejected judicial efforts to read remedies into federal statutes that Congress did not put there. *See, e.g., Sosa v. Alvarez-Machain*, 542 U.S. 692, 727 (2004); *Gonzaga Univ. v. Doe*, 536 U.S. 273, 285 (2002); *Sandoval*, 532 U.S. at 287-88; *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 173 (1994); *Touche Ross & Co. v. Redington*, 442

U.S. 560, 568 (1979). That restraint is more than a trend. It is a reflection of core separation of powers principles: Private rights of action to enforce federal law, like substantive federal law itself, must be created by Congress. *See Sandoval*, 532 U.S. at 286; *Touche Ross*, 442 U.S. at 578. A contrary view would amount to judicial encroachment on Congress's purview over the remedies available for violations of federal statutes. Today "it is settled that there is an implied cause of action only if the underlying statute can be interpreted to disclose the intent to create one." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008).

The Court has applied these settled principles even in cases involving alleged *constitutional* violations. In *Correctional Services Corporation v. Malesko*, 534 U.S. 61 (2001), this Court declined to infer a *Bivens* damages remedy for alleged constitutional violations by a government contractor operating a halfway house. Citing *Sandoval*, the Court explained that it had "abandoned" the *Borak* understanding of private rights of action "decades ago" and "retreated from our previous willingness to imply a cause of action where Congress has not provided one." 534 U.S. at 67 n.3. The Court has only reinforced this reluctance to infer private statutory and constitutional rights of action since *Malesko*. *See, e.g., Wilkie v. Robbins*, 551 U.S. 537 (2007); *see also Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1948 (2009) ("implied causes of action are disfavored").

This Court has thus been clear and consistent: Absent congressional intent to create a cause of action, "a cause of action *does not exist* and courts

*may not create one.*" *Sandoval*, 532 U.S. at 286-87 (emphases added). Other courts of appeals have correctly grasped and applied that message. *See Grochowski v. Phoenix Constr.*, 318 F.3d 80, 86 (2d Cir. 2003); *Hodges v. The Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414, 416 (10th Cir. 1984); *Hoopes v. Equifax, Inc.*, 611 F.2d 134, 135 (6th Cir. 1979); *cf. Buck v. Am. Airlines, Inc.*, 476 F.3d 29, 37 (1st Cir. 2007) (refusing "to abet a blatant evasion of the implied right of action doctrine" through state-law mechanisms).

The Ninth Circuit, in contrast, created a private cause of action here despite conceding that the statute did not. The court below lost sight of the fundamental point that whether a cause of action exists turns on whether Congress created one. The court concluded that "[a]lthough the statute mandating the [Pharmaceutical Pricing Agreement] does not create a federal private cause of action, allowing [respondent's] contract claim to go forward is consistent with Congress' intent in enacting the legislative scheme." Pet. App. 29a. That is a non-sequitur. If Congress had intended to create the claim that respondent seeks to bring, it would have provided an express cause of action. Congress did not enact such a cause of action, and the courts lack the authority to create it. *See Sandoval*, 532 U.S. at 286-87.

This Court did not take pains to articulate and reinforce these limits in decisions like *Sandoval*, *Stoneridge*, and *Malesko* just so the lower courts could nullify their practical effect by a simple resort to federal common law. If the decision below is correct, the analysis of whether a federal statute

creates a private damages action is largely academic; the conclusion that there is no statutory cause of action simply clears the way for the recognition of a federal common law cause of action. This gets matters backwards. This Court has, if anything, been more clear that the resort to the federal common law is disfavored. *See, e.g.*, *O'Melveny & Myers v. FDIC*, 512 U.S. 79, 87 (1994). Indeed, federal common law is a uniquely poor source of authority to trump the remedies determination made by Congress. While it remains a slight overstatement that "[t]here is no federal general common law," *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), any residual common-law authority in the federal courts is limited and "subject to the paramount authority of Congress," *Nw. Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95 (1981). Because the federal common law authority is strictly limited, lower courts should be doubly loath to use that disfavored device to fashion the disfavored remedy of an implied damages action to enforce a federal statute and evade this Court's precedents. But that is precisely what the Ninth Circuit accomplished in the decision below.

### B. The Ninth Circuit Erred By Creating A Damages Remedy Based On Its View Of The Policies At Issue.

The Ninth Circuit's decision appears to have been based on that court's view that the 340B statutory scheme does not provide adequate enforcement measures and thus that it was "sensible" to enlist 340B entities to assist the Government with enforcement. *See* Pet. App. 27a.

The Ninth Circuit emphasized that the 340B statute "does not 'expressly provide' any remedies to covered entities." Pet. App. 25a. And it suggested that HHS's authority to enforce the 340B program requirements against manufacturers was less than robust. *See* Pet. App. 26a. The court thus viewed empowering respondent as a private attorney general as "one way of ensuring that drug companies comply with their obligations," rather than "'plac[ing] the entire burden of enforcement' on the government." Pet. App. 27a (quoting *Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir. 1987)).

The Ninth Circuit's approach was wholly misplaced. The determination of how to structure a proper enforcement scheme is for Congress. The courts' job is to ascertain the remedies that Congress created. It is not to second-guess or try to improve upon Congress's judgment armed with nothing more than federal common law and a view of what is "sensible." *See Sandoval*, 532 U.S. at 286-87. In emphasizing that Congress had not provided any express remedies to 340B entities, the court below seemed motivated by a sense that *some* remedy *must* exist. But the absence of a statutory remedy is a rational determination, not an invitation for supplementation via federal common law. "Indeed, it is where Congress has intentionally withheld a remedy that we must most refrain from providing one because it is in those situations that 'appropriate judicial deference' is especially due . . . ." *Wilson v. Libby*, 535 F.3d 697, 709 (D.C. Cir. 2008) (quoting *Schweiker v. Chilicky*, 487 U.S. 412, 423 (1988)), *cert. denied*, 129 S. Ct. 2825 (2009).

The Ninth Circuit failed to recognize two critical facts that in the *Bivens* context would be called "special factors counseling hesitation." First, in examining the statutory remedies specific to the 340B program *in isolation*, the Ninth Circuit failed to recognize that the 340B program is inextricably linked to the Medicaid rebate program. AMP and BP were created under the Medicaid rebate program before the 340B program existed. They continue to be determined under that program and then simply carried over to serve the 340B program. Accordingly, the strength of the statutory remedies specific to the 340B program is largely beside the point as a practical matter, because the Medicaid rebate program is indisputably subject to vigorous enforcement by the Government. *See* U.S. CA9 Br. 28. Congress' decision not to create a private right of action for 340B entities was perfectly sensible because those entities in effect piggyback on the work done in the Medicaid rebate program to establish the prices used in the 340B program. There was and is no need for a separate mechanism, specific to the 340B program, to duplicate the enforcement structure in place to police compliance with Medicaid.

Second, in fashioning a federal common law remedy for third-party beneficiaries of government contracts, the Ninth Circuit ignored the existence of a wholly separate statutory regime designed to address the government contracts field: the False Claims Act ("FCA"). The FCA expressly creates a private right of action for damages, and quite a powerful one at that. Anyone can sue as a "relator" in the name of the United States, even without suffering individual injury. *See Vt. Agency of Nat.*

*Res. v. U.S. ex rel. Stevens*, 529 U.S. 765 (2000). The FCA provides for penalties on top of treble damages. 31 U.S.C. § 3729(a). Prevailing relators collect up to 30% of the "proceeds of the action or settlement" as a bounty, plus their attorney's fees. *Id.* § 3730(d)(2). The Government has obtained *billions* of dollars under the FCA in recent years. *See* U.S. Dep't of Justice, *Fraud Statistics*, http://www.justice.gov/opa/pr///fraud-statistics1986-2008.htm.

The point is not that respondent has a valid FCA remedy. If respondent could comply with all the demands of the FCA, including Fed. R. Civ. P. 9(b)'s particularized pleading standard for fraud and § 3729(b)(3)'s demanding standard for scienter, it presumably would be pursuing the treble damages remedy provided by Congress.[2] Rather, the point is that when Congress has enacted a statutory scheme to ensure fair dealing in contractual undertakings with the Government — especially one that allows non-contracting parties to sue in certain specifically designated situations, subject to specific limits — there is no role for a federal court to augment that

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[2] Respondent initially sued petitioners under California's False Claims Act, which tracks the federal FCA. *See* Pet. App. 99a-100a, 105a. After the district court dismissed the state FCA claim, respondent devised its third-party beneficiary theory and added a breach of contract claim. *See* Pet. App. 100a. After the district court held that respondent could not satisfy Fed. R. Civ. P. 9(b) and dismissed the state FCA claim a second time, respondent abandoned that claim. *See* Pet. App. 7a. Respondent has not acquired a more substantial basis for its claims as this litigation has extended into its sixth year and consumed extensive resources; the court below recognized that "the nature of the breaches [respondent] will seek to prove is unclear." Pet. App. 29a.

system by authorizing third-party beneficiaries to bring common law actions. The creation of federal common law is not simply disfavored, *see O'Melveny & Myers*, 512 U.S. at 87, but entirely inappropriate when an express cause of action occupies the field.

Finally, the Ninth Circuit's insistence that empowering 340B entities to sue will "help" the Government is mystifying. The Government, in response to the court's request, explained its view that "permitting [respondent's] challenge would conflict with Congress's comprehensive administrative and enforcement scheme, and accord [respondent] contract rights never intended by the PPA's signatories." U.S. CA9 Br. 13. It is remarkable enough that the court below believed that it knew better than the Government whether federal common law enforcement by 340B entities would be a "sensible" bolstering of the Government's enforcement authorities. *See* Pet. App. 27a. But it is truly astonishing that the court reached that conclusion without so much as mentioning the Government's statement that "HHS never imagined that a 340B entity could bring a third-party beneficiary lawsuit like [respondent's]." U.S. CA9 Br. 21.[3]

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[3] It goes without saying that drug manufacturers, the other parties to the PPA, also never "intended to grant covered [340B] entities enforceable rights" or foresaw third-party beneficiary litigation of this type. *See* Pet. App. 13a.

## II. THE DECISION BELOW WILL UNDERMINE THE REGULATORY SCHEME.

In addition to running counter to this Court's recent jurisprudence, the Ninth Circuit's decision will have sweeping ramifications on the regulatory scheme. While the Ninth Circuit suggested that the "ceiling prices" charged by drug manufacturers to 340B entities escape all oversight, the reality is far different. Manufacturers are required by law to report to HHS the two core components of the 340B ceiling price — AMP and BP. And HHS has the authority — the *exclusive* authority — to audit those reported price components. The regulatory scheme thus not only provides a mechanism for oversight of 340B ceiling prices, but it squarely delegates oversight responsibility to HHS. Congress correctly recognized that HHS is uniquely equipped to navigate the technical complexities of drug pricing, make reasonable policy judgments, balance competing interests, and impose uniform standards. By inviting the courts into the determination of AMP and BP at the behest of purported third-party beneficiaries, the decision below threatens far-reaching uncertainty, disuniformity, and destabilization.

### A. Private Enforcement Upends HHS's Exclusive And Expert Oversight Over The 340B Ceiling Price Components.

The 340B ceiling price is calculated from a formula based on the two inputs challenged by respondent — AMP and BP. Both inputs are part of the detailed Medicaid regulatory scheme. Congress requires drug manufacturers to report AMP and BP

at specified intervals to CMS as part of the Medicaid outpatient drug rebate program. *See* 42 U.S.C. § 1396r-8(b)(3)(A). Congress has also directed HHS to promulgate regulations offering guidance on how to calculate AMP. *See* Pub. L. No. 109-171, § 6001(c)(3)(B); 42 C.F.R. §§ 447.500-447.520. Moreover, Congress has supplied HHS with various enforcement tools to audit and investigate manufacturers' reported AMP and BP figures. *See* 42 U.S.C. § 1396r-8(b)(3)(A)-(B). HHS may levy monetary penalties if the figures are untimely or false, *see id.* § 1396r-8(b)(3)(B)-(C), or work with the Department of Justice to pursue False Claims Act remedies. *See id.* § 1396r-8(b)(3)(C)(ii). And HHS can impose the ultimate sanction — it can terminate the manufacturer's eligibility for Medicaid for good cause. *See id.* § 1396r-8(b)(4)(B).

The Ninth Circuit examined only the authorities created by the 340B statute itself, *see* Pet. App. 25a-27a, and its apparent belief that the 340B statute does not give HHS robust enforcement authorities thus misses the point. AMP and BP originated in the Medicaid rebate program before the 340B program was created in 1992. AMP and BP are determined and reported to CMS under the Medicaid rebate program. The ceiling price for the 340B program simply borrows these inputs from Medicaid. The Government's amicus brief explained that "[b]y focusing on [the Health Resources and Services Administration] and the 340B statute, [respondent] ignores the important role that CMS and the Social Security Act play in the 340B Program." U.S. CA9 Br. 27. Although respondent is a 340B entity rather than a state Medicaid agency, "to the extent that [respondent] is challenging

manufacturers' AMP and Best Price calculations, [respondent] is actually challenging figures reported to CMS as part of the Medicaid Rebate Program." *Id.* And the Government explained that, whatever may be the case with respect to the 340B program and HRSA in isolation, the Medicaid rebate program "has clearly been committed to CMS's comprehensive regulatory authority." *Id.*

As noted, however, the Ninth Circuit did not address the substance of the Government's amicus brief, and it made the same error as respondent by failing to recognize that CMS's oversight of the Medicaid rebate program amounts to oversight of the calculation of the 340B ceiling price. For the same reason, the court below failed to understand that the use of Medicaid pricing inputs in the 340B program means that "allowing suits like this would threaten the orderly operation of *both* programs." *Id.* at 19 (emphasis in original). Simply put, if a court orders a manufacturer to calculate AMP or BP in a particular way at the instance of a 340B entity, that same calculation will necessarily apply in the Medicaid rebate program. *See* 42 U.S.C. § 256b(b). There can only be one AMP and BP at a time for a given drug.

### B. Private Enforcement Will Generate Confusion And Conflicting Standards.

Private enforcement of the 340B program that aims to test its AMP and BP components cannot function in practice.

As an initial matter, the scope of the programs and operations implicated by this suit is massive. Approximately 150 innovator drug manufacturers

determine and report BP every calendar quarter for more than 6,300 drug products. These manufacturers and many more calculate and report AMP every month *and* every quarter for over 25,000 products. For each dosage form and strength of an innovator prescription drug, a manufacturer must therefore report four BPs and 16 AMPs every year. Many PhRMA members calculate and report over 50 of these Medicaid price points each reporting period. In 2003, drug manufacturers paid out over $6.5 billion in Medicaid rebates; 340B discounts in the same period totaled approximately $600 million.[4] The effect of AMP and BP in the Medicaid rebate program is thus an order of magnitude larger than in the 340B program.

The litigation burdens imposed by respondent's claims are staggering. Respondent challenges all AMPs and BPs reported by nine large manufacturers over the course of seven and a half years. *See* Pet. App. 74a. This claim implicates more than five thousand separate prices reported to CMS for hundreds of drug products. To support its allegation that petitioners overcharged it in unspecified ways, respondent seeks "[a]ll information . . . underlying [petitioners'] determinations of AMP and BP." *Id.* This, moreover, is but the "first stage of discovery." *Id.* Respondent then will have 40 pages to frame the additional discovery that it will seek at "Stage Two." Pet. App. 77a. If the decision below is permitted to stand, the entire industry will be subjected to

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[4] In 2009, the U.S. pharmaceutical and biotechnology industries paid out over $8.3 billion in Medicaid drug rebates.

disruptive and extraordinarily expensive third-party beneficiary fishing expeditions for years to come.

As burdensome as such litigation will be for manufacturers, the burden alone is not the worst problem. Private litigation also will generate uncertainty and inconsistency that will make ongoing compliance with Medicaid rebate program obligations nearly impossible. Determining AMP and BP is extremely complex and technical. The figures are calculated in dollars to six decimal places — to one *ten-thousandth* of a penny. Manufacturers have entire departments devoted to the calculation of government-reportable prices. They enlist expensive and sophisticated computer systems to track sales, customers, adjustments, discounts, rebates, price concessions, and other data just for this purpose. Manufacturers also employ legal and compliance officers trained specifically in the administration of pricing reporting requirements, who issue and oversee detailed internal policies and procedures. HHS is far better equipped to grasp and navigate these complexities than courts equipped only with federal common law.

Manufacturers must try to interpret ambiguous program requirements, often without clear (or any) HHS guidance. For example, manufacturers are required to allocate so-called "bundled" discounts across affected products. Yet important questions about what kinds of arrangements actually constitute bundles and how the attendant price concessions are to be allocated in practice remain unanswered and largely uncommented upon. Where HHS has yet to issue guidance on a specific interpretive issue, preserving the exclusivity of

HHS's oversight takes on even greater importance. HHS instructs that in such a situation, the manufacturer "may make reasonable assumptions in its calculations" of AMP and BP. Medicaid Drug Rebate Agreement § II(i). A "reasonable" assumption cannot be distinguished from an "unreasonable" one without specialized expertise and a deep understanding of the industry. And coherent guidance as to the proper treatment of ambiguous issues can only emerge if there is a single interpreter. HHS possesses that expertise and understanding, and HHS is the only entity in a position to provide uniform and definitive answers.

The Government itself has not yet come close to definitively resolving all the difficult questions that can arise in calculating AMP and BP. The tacit premise of respondent's claim appears to be that AMP and BP are governed by simple formulae, but that is very far from the truth. As the Government explained in the court below, "manufacturers must contend with many difficult issues of interpretation, including questions surrounding the definition of a 'wholesaler,' questions about the meaning of 'retail class of trade,' and questions about a variety of complex pricing arrangements." U.S. CA9 Br. 4-5. The broad definitions in the Medicaid rebate statute and the agreements thereunder raise as many questions as they answer. CMS has issued "Releases" containing ad hoc guidance over the years, but those Releases did not purport to provide comprehensive instructions. *See* U.S. CA9 Br. 5. There were no regulations from the 1991 inception of the program until 2007. *See* 72 Fed. Reg. 39,142 (July 17, 2007). Although the 103-page preamble and regulations published in 2007 went some

distance toward clarifying matters, they left significant interpretive issues and practical complexities unaddressed. *See* U.S. CA9 Br. 29 ("even working within CMS guidance, a number of difficult interpretive questions can arise"). And now the health care reform bills enacted in March 2010 have raised many new questions.

But if the issues are left to HHS, there is at least the possibility of clear answers ultimately emerging. The agency can provide guidance and the agency's position could be tested, subject to appropriate deference, under the APA. Under the Ninth Circuit's approach, every one of these unanswered details would be the subject of litigation. With courts guided by nothing more than the federal common law and their own conception of what is sensible, inconsistent rulings are certain to emerge.

But this is not a program where uncertain and inconsistent results can be tolerated. There can only be one AMP and one BP, applicable to both the 340B program and Medicaid. There cannot be different AMPs or BPs for a given drug in a given reporting period in different jurisdictions. This unitary, national system cannot be governed by multiple courts issuing disparate orders about how to determine these price points. Even where the court orders are not diametrically opposed — one court holding that sales to specialty pharmacies are included in AMP, and another court holding the opposite — it suffices for the orders to be even slightly different to destroy the nationwide uniformity on which these programs are premised. Given the wide scope for judgment calls in gray areas, it would not take much litigation to produce

different judicially-approved methodologies that would make nationwide uniformity impossible. Court orders arising out of this kind of litigation might also contradict CMS guidance, making simultaneous compliance with judicial and executive pronouncements impossible and putting drug manufacturers in an untenable bind.

In short, the reality of AMP and BP dictates flexibility and reliance on HHS's unique, centralized expertise. The type of mass litigation pursued by respondent, in contrast, presumes that if only manufacturers are dragged through enough discovery, 340B entities and courts will be able to ascertain the "correct" figures and that any departure from those figures reflects a breach of contract. Once the regulatory scheme is understood, however, it is crystal clear that opening the door to private enforcement through damages actions is not at all compatible with the orderly operation of either the 340B program or the Medicaid rebate program. The Ninth Circuit was able to declare that recognizing a federal common law claim was "wholly compatible with the Section 340B program's objectives," Pet. App. 26a, only because it did not address the Government's explanation of how the 340B program takes its pricing inputs from the Medicaid rebate program such that "allowing suits like this would threaten the orderly operation of *both* programs." U.S. CA9 Br. 19 (emphasis in original).

### C. States And 340B Entities Have Conflicting Interests That Further Undermine The Ninth Circuit's Simplistic Model Of Third-Party Beneficiary Suits.

The Ninth Circuit's notion that 340B entities are the intended beneficiaries of the 340B contracts fails to appreciate the complexity of the regulatory regime generally and the interrelationship between the Medicaid rebate program and the 340B program in particular. The Government uses AMP both to set the amount manufacturers must pay in Medicaid rebates to States and to establish the 340B ceiling price that may be charged to 340B entities. The interests of States and 340B entities in this respect are often directly opposite. In most circumstances, the lower the AMP, the lower a product's price to a 340B entity. Conversely, in most circumstances, the higher the AMP, the more a state Medicaid agency receives in rebates from manufacturers. On the myriad issues for which there is no definitive statutory or regulatory guidance, 340B entities will advocate an interpretation that reduces AMP, while States will advocate an interpretation that increases it.

Thus, this is not a simple matter where the Government insists on a provision in a contract for the exclusive benefit of an identifiable third party. The critical pricing metrics that respondent seeks to attack are not designed for 340B entities' benefit, but are the product of a more complicated regulatory system that serves multiple ends. Resolution of the competing demands in that complex program should be undertaken deliberately by the political branches.

It should not be displaced by a crazy-quilt of judicial decisions driven by a race to litigate.

* * * *

The Ninth Circuit recognized that the relevant statute did not provide an express cause of action. Rather than accept the consequences of Congress's decision not to authorize private damages actions and follow this Court's lead in swearing "off the habit of venturing beyond Congress's intent," the Ninth Circuit could not resist respondent's "invitation to have one last drink." *Sandoval*, 532 U.S. at 287. That decision would merit correction even if the decision did not threaten immediate and severe disruption to important health care programs. The scale and immediacy of the harm that the decision below will cause reinforces the need for this Court's review now.

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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# JOINT APPENDIX

Supreme Court, U.S.
NOV 12 2010
OFFICE OF THE CLERK

No. 09-1273

IN THE

# Supreme Court of the United States

ASTRA USA, INC., *et al.*,
*Petitioners*,

v.

COUNTY OF SANTA CLARA,
ON BEHALF OF ITSELF AND ALL
OTHERS SIMILARLY SITUATED,
*Respondent*.

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## JOINT APPENDIX

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT
OF CALIFORNIA

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COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

v.

ASTRA USA, INC., *et al.*,

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**RELEVANT DOCKET ENTRIES**

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 09/15/2005 | 1 | NOTICE OF REMOVAL OF ACTION UNDER 28 U.S.C. 1441 (DIVERSITY AND FEDERAL QUESTION JURISDICTION) from Superior Court of California County of Alameda. Their case number is G05228108. (Filing fee $250.00 receipt number 3376511). Filed by AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corporation, Bristol-Myers Squibb Company, Burroughs Wellcome Co, Glaxo Wellcome Inc., Pfizer Inc., Schering-Plough Corporation, Tap Pharmaceutical Products Inc, Wyeth-Ayerst Laboratories, Inc, Zeneca Inc, ZLB Behring, LLC, Astra USA, Inc. (aaa, Court Staff) (Filed on 9/15/2005) Additional attachment(s) added on 9/19/2005 (aaa, Court Staff). Additional |

| Date Filed | # | DOCKET TEXT |
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| | | attachment(s) added on 9/19/2005 (aaa, Court Staff). Additional attachment(s) added on 9/19/2005 (aaa, Court Staff). Additional attachment(s) added on 9/19/2005 (aaa, Court Staff). Additional attachment(s) added on 9/19/2005 (aaa, Court Staff). (Entered: 09/16/2005) |
| | | * * * |
| 10/17/2005 | 61 | MOTION for Joinder *PLAINTIFF'S NOTICE OF MOTION AND MOTION FOR JOINDER, REMAND AND/OR DISMISSAL* filed by The County of Santa Clara. Motion Hearing set for 11/17/2005 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Mottek, Jacqueline) (Filed on 10/17/2005) (Entered: 10/17/2005) |
| | | * * * |
| 12/02/2005 | 93 | ORDER by Judge Alsup denying 68 Motion for Remand or Dismissal, denying motion for Joinder and granting requests for judicial notice. (whalc2, COURT STAFF) (Filed on 12/2/2005) (Entered: 12/02/2005) |
| | | * * * |
| 12/15/2005 | 99 | MOTION to Amend/Correct *COMPLAINT* filed by The County of Santa Clara. Motion Hearing set for |

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| | | 1/19/2006 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Mottek, Jacqueline) (Filed on 12/15/2005) (Entered: 12/15/2005) |
| | | * * * |
| 12/29/2005 | 106 | Memorandum in Opposition 99 *Statement of Non-Opposition to Plaintiff's Motion to Amend Complaint* filed by Bayer Corporation. (Ezgar, Geoffrey) (Filed on 12/29/2005) Modified on 1/3/2006 (sis, COURT STAFF). (Entered: 12/29/2005) |
| | | * * * |
| 01/03/2006 | 107 | ORDER by Judge Alsup granting 99 Motion to Amend/Correct ; County of Santa Clara is required to E-FILE the amended document (whalc2, COURT STAFF) (Filed on 1/3/2006) (Entered: 01/03/2006) |
| | | * * * |
| 01/03/2006 | 110 | MOTION to Dismiss *pursuant to FRCP 8, 9(b) and 12(b)(6), on behalf of all defendants* filed by AstraZeneca Pharmaceuticals LP, Zeneca Inc, Astra USA, Inc. Motion Hearing set for 2/9/2006 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Mayo, Sharon) (Filed on 1/3/2006) (Entered: 01/03/2006) |
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| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 01/09/2006 | 113 | AMENDED COMPLAINT *First Amended Complaint for Accounting Disclosure, for Violation of California Unfair Competition Law, For Violation of California False Claims Act, and For Unjust Enrichment* against AmerisourceBergen Corporation, Cardinal Health, Inc., HealthCare Purchasing Partners International, LLC, McKesson Corporation, SmithKline Beecham Corporation, dba GlaxoSmithKline, Wyeth Pharmaceuticals Inc., Wyeth, Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corporation, Bristol-Myers Squibb Company, Pfizer Inc., Schering-Plough Corporation, Tap Pharmaceutical Products Inc, Zeneca Inc, ZLB Behring, LLC, Astra USA, Inc. Filed by The County of Santa Clara. (Mottek, Jacqueline) (Filed on 1/9/2006) (Entered: 01/09/2006) |
| | | * * * |
| 01/19/2006 | 116 | Memorandum in Opposition re 110 MOTION to Dismiss *pursuant to FRCP 8, 9(b) and 12(b)(6), on behalf of all defendants PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS PURSUANT TO FED. R. CIV. P. 8, 9(b), AND 12(b)(6)* filed by The County of |

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| | | Santa Clara. (Mottek, Jacqueline) (Filed on 1/19/2006) (Entered: 01/19/2006) |
| | | * * * |
| 01/26/2006 | 118 | REPLY BRIEF IN SUPPORT OF MOTION to Dismiss 110 filed by AstraZeneca Pharmaceuticals LP, Zeneca Inc, Astra USA, Inc. Motion Hearing set for 2/9/2006 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Mayo, Sharon) (Filed on 1/26/2006) Modified on 1/27/2006 (sis, COURT STAFF). (Entered: 01/26/2006) |
| | | * * * |
| 02/14/2006 | 143 | ORDER GRANTING MOTION TO DISMISS by Judge William Alsup [granting 108 Motion to Dismiss, granting 110 Motion to Dismiss]. (whasec, COURT STAFF) (Filed on 2/14/2006) (Entered: 02/14/2006) |
| | | * * * |
| 02/28/2006 | 146 | AMENDED COMPLAINT *SECOND AMENDED COMPLAINT FOR ACCOUNTING DISCLOSURE, VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW, VIOLATION OF CALIFORNIA FALSE CLAIMS ACT, NEGLIGENCE, BREACH OF CONTRACT, BREACH OF COVENANT OF* |

| Date Filed | # | DOCKET TEXT |
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| | | *GOOD FAITH AND FAIR DEALING, AND QUANTUM MERUIT* against AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corporation, Bristol-Myers Squibb Company, Pfizer Inc., Schering-Plough Corporation, Tap Pharmaceutical Products Inc, AmerisourceBergen Corporation, Cardinal Health, Inc., HealthCare Purchasing Partners International, LLC, McKesson Corporation, SmithKline Beecham Corporation, dba GlaxoSmithKline, Wyeth Pharmaceuticals Inc., Wyeth, Inc., Zeneca Inc, ZLB Behring, LLC, Astra USA, Inc. Filed by The County of Santa Clara. (Attachments: # 1 Exhibit Exhibit A - Part 1 of 6# 2 Exhibit Exhibit A - Part 2 of 6# 3 Exhibit Exhibit A - Part 3 of 6# 4 Exhibit Exhibit A - Part 4 of 6# 5 Exhibit Exhibit A - Part 5 of 6# 6 Exhibit Exhibit A - Part 6 of 6# 7 Exhibit Exhibit B) (Mottek, Jacqueline) (Filed on 2/28/2006) (Entered: 02/28/2006) |
| | | * * * |
| 03/14/2006 | 149 | MOTION to Dismiss *plaintiff's Second Amended Complaint* filed by AstraZeneca Pharmaceuticals LP, Zeneca Inc, Astra USA, Inc. Motion Hearing set for 4/20/2006 08:00 AM |

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| | | in Courtroom 9, 19th Floor, San Francisco. (Attachments: # 1 Exhibit A) (Mayo, Sharon) (Filed on 3/14/2006) (Entered: 03/14/2006) |
| | | * * * |
| 03/30/2006 | 160 | Memorandum in Opposition re 149 MOTION to Dismiss *plaintiff's Second Amended Complaint Plaintiffs' Opposition to Defendants' Motion to Dismiss Second Amended Complaint Pursuant to Fed. R. Civ. P. 9(b) and 12(b)(6)* filed by The County of Santa Clara. (Mottek, Jacqueline) (Filed on 3/30/2006) (Entered: 03/30/2006) |
| | | * * * |
| 04/06/2006 | 170 | Reply Memorandum re 149 MOTION to Dismiss *plaintiff's Second Amended Complaint filed on behalf of all manufacturer defendants* filed by AstraZeneca Pharmaceuticals LP, Zeneca Inc, Astra USA, Inc. (Mayo, Sharon) (Filed on 4/6/2006) (Entered: 04/06/2006) |
| | | * * * |
| 05/17/2006 | 196 | ORDER by Judge Alsup granting in part and denying in part 149 Motion to Dismiss, finding as moot 155 Motion to Dismiss. (whalc2, COURT STAFF) (Filed on 5/17/2006) (Entered: 05/17/2006) |

| Date Filed | # | DOCKET TEXT |
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| 06/02/2006 | 202 | MOTION to Amend/Correct *PLAINTIFFS' [CORRECTED] NOTICE OF MOTION AND MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT* filed by The County of Santa Clara. Motion Hearing set for 7/13/2006 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Mottek, Jacqueline) (Filed on 6/2/2006) (Entered: 06/02/2006) |
| | | * * * |
| 06/22/2006 | 206 | Memorandum in Opposition 202 *to plaintiff's motion for leave to file third amended complaint (filed on behalf of all defendants)* filed by AstraZeneca Pharmaceuticals LP, Zeneca Inc, Astra USA, Inc. (Attachments: # 1) (Mayo, Sharon) (Filed on 6/22/2006) Modified on 6/23/2006 (sis, COURT STAFF). (Entered: 06/22/2006) |
| | | * * * |
| 07/06/2006 | 209 | Reply Memorandum 198 *PLAINTIFFS' REPLY MEMORANDUM IN SUPPORT OF MOTION FOR LEAVE TO FILE THIRD AMENDED COMPLAINT* filed by The County of Santa Clara. (Lawrence, Jeffrey) (Filed on 7/6/2006) Modified |

| Date Filed | # | DOCKET TEXT |
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| | | on 7/7/2006 (sis, COURT STAFF). (Entered: 07/06/2006) |
| | | * * * |
| 07/28/2006 | 212 | ORDER by Judge Alsup denying 202 Motion for Leave to File Third Amended Complaint. Action dismissed with prejudice. (whalc2, COURT STAFF) (Filed on 7/28/2006) (Entered: 07/28/2006) |
| 07/28/2006 | 213 | JUDGMENT in favor of Astra USA, Inc.; AstraZeneca Pharmaceuticals LP; Aventis Pharmaceuticals, Inc.; Bayer Corp.; Bristol-Myers Squibb Co.; Pfizer, Inc.; Schering-Plough Corp.; SmithKline Beecham Corp.; TAP Pharmaceutical Products, Inc.; Wyeth, Inc.; Wyeth Pharmaceuticals, Inc.; Zeneca, Inc.; ZLB Behring LLC against County of Santa Clara. Signed by Judge Alsup on 7/28/06. (whalc2, COURT STAFF) (Filed on 7/28/2006) (Entered: 07/28/2006) |
| | | * * * |
| 08/11/2006 | 216 | NOTICE OF APPEAL as to 212 Order on Motion to Amend/Correct, 213 Judgment, by The County of Santa Clara. Filing fee $455, receipt number 3388848. (sis, COURT STAFF) (Filed on 8/11/2006) (Entered: 08/11/2006) |
| | | * * * |

| Date Filed | # | DOCKET TEXT |
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| 08/17/2006 | | USCA Case Number 06-16471 Ninth Circuit for 216 Notice of Appeal filed by The County of Santa Clara. (sis, COURT STAFF) (Filed on 8/17/2006) (Entered: 08/17/2006) |
| | | * * * |
| 09/02/2008 | 225 | ORDER of USCA- Decision of the District Court is Reversed and Remanded as to 216 Notice of Appeal filed by The County of Santa Clara (sis, COURT STAFF) (Filed on 9/2/2008) (Entered: 09/02/2008) |
| | | * * * |
| 10/09/2008 | 244 | MOTION for Protective Order *on behalf of all defendants* filed by Schering-Plough Corporation. Motion Hearing set for 11/13/2008 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Kemp, Colin) (Filed on 10/9/2008) (Entered: 10/09/2008) |
| | | * * * |
| 10/24/2008 | 261 | Memorandum in Opposition re 244 MOTION for Protective Order *on behalf of all defendants PLAINTIFF'S [CORRECTED] OPPOSITION TO DEFENDANTS' MOTION FOR PROTECTIVE ORDER* filed by The County of Santa Clara. (Lawrence, Jeffrey) (Filed on 10/24/2008) (Entered: 10/24/2008) |
| | | * * * |

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 10/30/2008 | 263 | Reply Memorandum re 244 MOTION for Protective Order *on behalf of all defendants filed by* Schering-Plough Corporation. (Hasson, Kirke) (Filed on 10/30/2008) (Entered: 10/30/2008) |
| | | * * * |
| 11/25/2008 | 269 | ORDER GRANTING MOTION FOR PROTECTIVE ORDER AND CERTIFYING INTERLOCUTORY APPEAL PURSUANT TO 28 U.S.C. 1292(b) by Judge Alsup granting 244 Motion for Protective Order (whalc2, COURT STAFF) (Filed on 11/25/2008) (Entered: 11/25/2008) |
| | | * * * |
| 12/01/2008 | 271 | MOTION for Leave to File *PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR LEAVE TO ADD NEW PARTIES (PLAINTIFFS ONLY) AND FILE THIRD AMENDED COMPLAINT* filed by The County of Santa Cruz, The County of Riverside, The County of Santa Clara. Motion Hearing set for 1/8/2009 08:00 AM in Courtroom 9, 19th Floor, San Francisco. (Lawrence, Jeffrey) (Filed on 12/1/2008) (Entered: 12/01/2008) |
| | | * * * |

| Date Filed | # | DOCKET TEXT |
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| 12/18/2008 | 280 | Reply Memorandum re 271 MOTION for Leave to File *PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR LEAVE TO ADD NEW PARTIES (PLAINTIFFS ONLY) AND FILE THIRD AMENDED COMPLAINT MOTION* for Leave to File *PLAINTIFFS' NOTICE OF MOTION AND MOTION FOR LEAVE TO ADD NEW PARTIES (PLAINTIFFS ONLY) AND FILE THIRD AMENDED COMPLAINT* filed by AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corporation, Bristol-Myers Squibb Company, Burroughs Wellcome Co, Glaxo Wellcome Inc., Pfizer Inc., Schering-Plough Corporation, SmithKline Beecham Corp., Tap Pharmaceutical Products Inc, Wyeth-Ayerst Laboratories, Inc, HealthCare Purchasing Partners International, LLC, Zeneca Inc, ZLB Behring, LLC, Astra USA, Inc. (Fischer, Matthew) (Filed on 12/18/2008) (Entered: 12/18/2008) |
| | | * * * |
| 12/19/2008 | 283 | ORDER GRANTING PLAINTIFFS' MOTION FOR LEAVE TO ADD NEW PARTIES AND FILE THIRD AMENDED COMPLAINT by Judge Alsup granting 271 Motion for Leave to File (whalc2, COURT |

| Date Filed | # | DOCKET TEXT |
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| | | STAFF) (Filed on 12/19/2008) (Entered: 12/19/2008) |
| 12/23/2008 | 284 | AMENDED COMPLAINT *THIRD AMENDED COMPLAINT FOR BREACH OF CONTRACT* against AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corporation, Bristol-Myers Squibb Company, Pfizer Inc., Schering-Plough Corporation, Tap Pharmaceutical Products Inc, SmithKline Beecham Corporation, dba GlaxoSmithKline, Wyeth Pharmaceuticals Inc., Wyeth, Inc., Zeneca Inc, ZLB Behring, LLC, Astra USA, Inc. Filed by The County of Santa Clara, The County of Santa Cruz, The County of Riverside. (Attachments: # 1 Exhibit A - Part 1 of 6, # 2 Exhibit A - Part 2 of 6, # 3 Exhibit A - Part 3 of 6, # 4 Exhibit A - Part 4 of 6, # 5 Exhibit A - Part 5 of 6, # 6 Exhibit A - Part 6 of 6, # 7 Exhibit B, # 8 Exhibit C, # 9 Exhibit D, # 10 Exhibit E - Part 1 of 3, # 11 Exhibit E - Part 2 of 3, # 12 Exhibit E - Part 3 of 3, # 13 Exhibit F) (Lawrence, Jeffrey) (Filed on 12/23/2008) (Entered: 12/23/2008) |
| | | * * * |
| 02/03/2009 | 310 | USCA ORDER - Petition for Permission to Appeal is Granted. (sis, |

| Date Filed | # | DOCKET TEXT |
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| | | COURT STAFF) (Filed on 2/3/2009) (Entered: 02/03/2009) |
| | | * * * |
| 05/05/2009 | 364 | ORDER REGARDING CLASS CERTIFICATION denying 317 Motion to Certify Class; granting 343 Motion to Seal; granting 345 Motion to Seal Document; denying 352 Motion in Limine (whalc2, COURT STAFF) (Filed on 5/5/2009) (Entered: 05/05/2009) |
| | | * * * |
| 12/15/2009 | 542 | ORDER of USCA- mandate issued 09/18/08 is hereby recalled as to 216 Notice of Appeal filed by The County of Santa Clara (sis, COURT STAFF) (Filed on 12/15/2009) (Entered: 12/17/2009) |
| 12/15/2009 | 543 | USCA Opinion- Reversed and remanded as to 216 Notice of Appeal filed by The County of Santa Clara (sis, COURT STAFF) (Filed on 12/15/2009) (Entered: 12/17/2009) |
| 12/15/2009 | 544 | MANDATE of USCA - This court vacates the District Court's order granting motion for protective order and remands for further proceedings consistent with the opinion filed concurrently in 06/16471 as to 216 Notice of Appeal filed by The County of Santa Clara (sis, COURT |

| Date Filed | # | DOCKET TEXT |
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| | | STAFF) (Filed on 12/15/2009) (Entered: 12/17/2009) |
| | | * * * |
| 02/04/2010 | 569 | Declaration of David Brown in Support of 564 Joint MOTION for Judgment on the Pleadings *(Partial) Or, In the Alternative, for Protective Order* Joint MOTION for Judgment on the Pleadings *(Partial) Or, In the Alternative, for Protective Order Joint MOTION for Judgment on the Pleadings (Partial) Or, In the Alternative, for Protective Order (with Exhibits A1 and A2)* filed by SmithKline Beecham Corporation, dba GlaxoSmithKline, SmithKline Beecham Corp. (Related document(s) 564) (Kemp, Colin) (Filed on 2/4/2010) (Entered: 02/04/2010) |
| | | * * * |
| 02/04/2010 | 571 | Declaration of Kathleen Dynan Black in Support of 564 Joint MOTION for Judgment on the Pleadings *(Partial) Or, In the Alternative, for Protective Order* Joint MOTION for Judgment on the Pleadings *(Partial) Or, In the Alternative, for Protective Order* Joint MOTION for Judgment on the Pleadings *(Partial) Or, In the Alternative, for Protective Order* filed by Wyeth Pharmaceuticals Inc., Wyeth, |

| Date Filed | # | DOCKET TEXT |
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| | | Inc., Wyeth-Ayerst Laboratories, Inc. (Related document(s) 564) (Kemp, Colin) (Filed on 2/4/2010) (Entered: 02/04/2010) |
| | | * * * |
| 02/04/2010 | 574 | Declaration of Paul Le Compte in Support of 564 Joint MOTION for Judgment on the Pleadings *(Partial) Or, In the Alternative, for Protective Order* Joint MOTION for Judgment on the Pleadings *(Partial) Or, In the Alternative, for Protective Order* Joint MOTION for Judgment on the Pleadings *(Partial) Or, In the Alternative, for Protective Order* filed by Pfizer Inc.. (Related document(s) 564) (Kemp, Colin) (Filed on 2/4/2010) (Entered: 02/04/2010) |
| | | * * * |
| 02/12/2010 | 586 | ORDER of USCA - Appellee's petitions for rehearing or rehearing en banc are denied as to 216 Notice of Appeal filed by The County of Santa Clara (sis, COURT STAFF) (Filed on 2/12/2010) (Entered: 02/16/2010) |
| | | * * * |
| 03/19/2010 | 605 | ORDER REGARDING DISCOVERY AND DENYING DEFENDANTS' MOTION FOR PARTIAL JUDGMENT ON THE PLEADINGS by Judge William Alsup |

| Date Filed | # | DOCKET TEXT |
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| | | [denying 555 Motion for Protective Order; granting in part and denying in part 557 Motion to Stay; denying 559 Motion for Protective Order; denying 564 Motion for Judgment on the Pleadings; granting in part and denying in part 592 Motion to Compel]. (whasec, COURT STAFF) (Filed on 3/19/2010) (Entered: 03/19/2010) |
| | | * * * |
| 09/30/2010 | 740 | ORDER STAYING ACTION PENDING DECISION FROM U.S. SUPREME COURT. Signed by Judge Alsup on September 30, 2010. (whalc2, COURT STAFF) (Filed on 9/30/2010) (Entered: 09/30/2010) |
| | | * * * |
| 10/07/2010 | 744 | ORDER of Supreme Court of the United States. The petition for a writ of certiorari is granted; as to 216 Notice of Appeal filed by The County of Santa Clara. No. 09-1273 (wsn, COURT STAFF) (Filed on 10/7/2010) (Entered: 10/08/2010) |

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 06-16471

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

v.

ASTRA USA, INC., *et al.*,

**RELEVANT DOCKET ENTRIES**

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 08/15/2006 | 2 | DOCKETED CAUSE AND ENTERED APPEARANCES OF COUNSEL. CADS SENT (Y/N): y. setting schedule as follows: CADS is past due; CADS must be filed no later than 8/22/06; appellant's designation of RT is due 8/21/06; appellee's designation of RT is due 8/31/06,, ; appellant shall order transcript by 9/11/06; court reporter shall file transcript in DC by 10/11/06; certificate of record shall be filed by 10/18/06; appellant's opening brief is due 11/27/06; appellees' brief is due 12/27/06,, ; appellants' reply brief is due 1/10/07; [06-16471] (GR) |

* * *

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 11/22/2006 | 10 | Filed original and 15 copies Appellant County of Santa Clara's opening brief (Informal: no) 31 pages; 5 excerpts of record in 2 Exc.vol; served on 11/22/06 minor defcy: no stmt of rel cases; Notified counsel. [06-16471] (BJB) |
| | | * * * |
| 01/17/2007 | 19 | Filed original and 15 copies aples 45 pages brief, 1 Exc. vols: ; served on 1/17/07 [06-16471] (CW) |
| | | * * * |
| 02/20/2007 | 31 | Filed original and 15 copies County of Santa Clara reply brief, (Informal: no) 14 pages; 5 suppl eor in 1 vol; served on 2/20/07 [06-16471] (BJB) |
| | | * * * |
| 03/11/2008 | 46 | ARGUED AND SUBMITTED TO STEPHEN R. REINHARDT, MELVIN BRUNETTI and RAYMOND C. FISHER. (DT) |
| 08/27/2008 | 47 | FILED OPINION (STEPHEN R. REINHARDT, MELVIN BRUNETTI and RAYMOND C. FISHER) REVERSED AND REMANDED. FILED AND ENTERED JUDGMENT. (RP) |
| 09/18/2008 | 48 | MANDATE ISSUED. (SR, MB and RCF) (GV) |

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 12/09/2009 | 49 | Filed Order for PUBLICATION (STEPHEN R. REINHARDT, BARRY G. SILVERMAN and RAYMOND C. FISHER) The mandate issued September 18, 2008, is hereby recalled. The opinion filed August 27, 2008, *see County of Santa Clara v. Astra USA, Inc.*, 540 F.3d 1094 (9th Cir. 2008), is withdrawn. A superseding opinion will be filed concurrently with this order. Petitions for rehearing or petitions for rehearing en banc may be filed. [7156687] (RP) |
| | | * * * |
| 12/09/2009 | 52 | FILED OPINION (STEPHEN R. REINHARDT, BARRY G. SILVERMAN and RAYMOND C. FISHER) REVERSED AND REMANDED, Judge: RCF Authoring. FILED AND ENTERED JUDGMENT. [7157151] (RP) |
| | | * * * |
| 12/30/2009 | 56 | Filed (ECF) Appellees Astra USA, Inc., AstraZeneca Pharmaceuticals LP and Zeneca Inc. petition for panel rehearing and petition for rehearing en banc (from 12/09/2009 opinion). Date of service: 12/30/2009. [7179437] (SDM) |

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 02/11/2010 | 57 | Filed order (STEPHEN R. REINHARDT, BARRY G. SILVERMAN and RAYMOND C. FISHER) The panel judges have voted to deny Appellees' petition for rehearing or rehearing en banc. The full court has been advised of the petition for rehearing en banc and no judge has requested a vote on whether to rehear the matter en banc. Fed. R. App. P. 35. Appellees' petition for rehearing or rehearing en banc, filed December 30, 2009, is DENIED. [7228889] (SC) |
| 02/19/2010 | 58 | MANDATE ISSUED. (SR, BGS and RCF) [7237759] (GV) |
| 04/23/2010 | 59 | Received notice from the Supreme Court: petition for certiorari filed on 04/21/2010. Supreme Court Number 09-1273. [7316614] (GV) |
| 09/28/2010 | 60 | Received notice from the Supreme Court. Petition for certiorari GRANTED on 09/28/2010. Supreme Court Number 09-1273. [7490273] (GV) |

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 08-80200

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

v.

ASTRA USA, INC., *et al.*,

**RELEVANT DOCKET ENTRIES**

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 12/11/2008 | 1 | FILED ON 12/11/2008 ORIGINAL AND 4 COPIES OF PETITION FOR PERMISSION TO APPEAL PURSUANT TO RULE 1292(b). SERVED ON 12/10/2008. (HC) |
| | | * * * |
| 12/22/2008 | 3 | FILED ON 12/11/2008 ORIGINAL AND 4 COPIES OF PETITION FOR PERMISSION TO APPEAL PURSUANT TO RULE 1292(b). SERVED ON 12/10/2008. (HC) |
| 02/03/2009 | 4 | Order filed (STEPHEN R. REINHARDT, MELVIN BRUNETTI and RAYMOND C. FISHER) The petition for permission to appeal pursuant to 28 U.S.C. § 1292(b) is granted. Within 10 days of this order, petitioner shall perfect the |

| Date Filed | # | DOCKET TEXT |
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| | | appeal pursuant to Federal Rule of Appellate Procedure 5(d). Petitioner's request to assign this appeal to the panel that heard the appeal in *County of Santa Clara v. Astra USA, Inc. et al.*, 06-16471, is granted. The following briefing schedule shall govern the perfected appeal: the opening brief and excerpts of record shall be due March 16, 2009, the answering brief shall be due April 15, 2009, and the optional reply shall be due within 14 days after service of the answering brief. (BJB) |

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 09-15216

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

v.

ASTRA USA, INC., *et al.*,

**RELEVANT DOCKET ENTRIES**

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 02/03/2009 | 1 | Filed order (STEPHEN R. REINHARDT, MELVIN BRUNETTI and RAYMOND C. FISHER) The petition for permission to appeal pursuant to 28 USC 1292(b) is granted. Within 10 days of this order, petitioner shall perfect the appeal pursuant to FRAP 5(d). Petitioner's request to assign this appeal to the panel that heard the appeal in *County of Santa Clara v. Astra USA, Inc, et al*, 06-16471 is granted. The following briefing schedule shall govern the perfected appeal: the opening brief and excerpts of record shall be due 3/16/09; the answering brief shall be due 4/15/09; and the optional reply brief shall be due within 14 days after |

| Date Filed | # | DOCKET TEXT |
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| | | service of the answering brief. [08-80200] (GR) |
| | | * * * |
| 03/16/2009 | 6 | Submitted (ECF) Opening brief for review. Submitted by Appellant County of Santa Clara. Date of service: 03/16/2009. [6846193] (SS) |
| | | * * * |
| 03/16/2009 | 8 | Filed Appellant County of Santa Clara excerpts of record in 4 volumes. Served on 03/16/2009 (WP) |
| | | * * * |
| 04/15/2009 | 13 | Submitted (ECF) Answering brief for review. Submitted by Appellees Astra USA, Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals, Inc., Bayer Corporation, Bristol-Myers Squibb Company, Pfizer, Inc., Schering-Plough Corporation, SmithKline Beecham Corporation, SmithKline Beecham Corporation, Tap Pharmaceutical Products, Inc., Wyeth Pharmaceuticals, Inc., Wyeth, Inc. and ZLB Behring LLC. Date of service: 04/15/2009. [6884317] (FCA) |
| 04/15/2009 | 14 | Filed Appellees Wyeth Pharmaceuticals, Inc. and Wyeth, Inc. excerpts of record in 1 volume. Served on 04/15/2009 (WP) |

| Date Filed | # | DOCKET TEXT |
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| | | * * * |
| 05/04/2009 | 16 | Submitted (ECF) Reply brief for review. Submitted by Appellant County of Santa Clara. Date of service: 05/04/2009. [6906598] (SS) |
| | | * * * |
| 07/28/2009 | 25 | Filed order (STEPHEN R. REINHARDT, MELVIN BRUNETTI and RAYMOND C. FISHER) The court invites the views of the Secretary of Health and Human Services on the following issue presented in this appeal: SEE ORDER FOR TEXT. If the Secretary wishes to file a brief as amicus curiae responding to this order, it is granted leave to do so pursuant to Federal Rule of Appellate Procedure 29(a). The brief should be filed no later than 45 days from the filed date of this order and comply with the page or type-volume limitations set forth in Federal Rules of Appellate Procedure 29(d) and 32(a)(7). Parties who are registered for ECF must file the supplemental brief electronically without submission of paper copies. Parties who are not registered ECF filers must file the original supplemental brief plus 4 paper copies. [7005541] (SC) |
| | | * * * |

| Date Filed | # | DOCKET TEXT |
|---|---|---|
| 10/27/2009 | 32 | Submitted (ECF) Amicus brief for review. Submitted by *Amicus Curiae* USA. Date of service: 10/27/2009. [7109330] (BMS) |
| | | * * * |
| 12/09/2009 | 46 | Order filed (STEPHEN R. REINHARDT, BARRY G. SILVERMAN and RAYMOND C. FISHER) We vacate the district court's November 25, 2008 Order Granting Motion for Protective Order and remand for further proceedings consistent with the opinion filed concurrently in No. 06-16471. Therefore, oral argument scheduled for Wednesday, December 23, 2009 is canceled and the appeal in this case is dismissed as moot. A certified copy of this order to the district court will constitute the mandate of this court. [] [7156642] (RP) |

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

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No. C-05-03740-WHA

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THE COUNTY OF SANTA CLARA,
ON BEHALF OF ITSELF AND ALL
OTHERS SIMILARLY SITUATED,
*Plaintiff*,

vs.

ASTRA USA, INC. *et al.*,
*Defendants*.

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CLASS ACTION

SECOND AMENDED COMPLAINT FOR ACCOUNTING DISCLOSURE, VIOLATION OF CALIFORNIA UNFAIR COMPETITION LAW, VIOLATION OF CALIFORNIA FALSE CLAIMS ACT, NEGLIGENCE, BREACH OF CONTRACT, BREACH OF COVENANT OF GOOD FAITH AND FAIR DEALING, AND *QUANTUM MERUIT*

DEMAND FOR JURY TRIAL

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## PRELIMINARY STATEMENT

1. This action is filed by plaintiffs, the County of Santa Clara, a public entity which owns, operates and provides health services by and through the Santa Clara Valley Health and Hospital System, and its various clinics and subdivisions, including the following: Santa Clara Valley Medical Center, Surgical Daycare 5 West, Electro Encephalography,

Oncology Clinic, Moorpark Clinic Pharmacy, Silver Creek Clinic Pharmacy, Out Patient Clinic Pharmacy, East Valley Clinic Pharmacy, South Valley Clinic Pharmacy, Valley Health Center Clinic Pharmacy, Chronic Peritoneal Dialysis—Home, Renal Dialysis, Emergency Department, East Valley Clinic, South Valley Clinic, Silver Creek Clinic, Valley Health Center Administration, MPC Primary Care, Valley Health Center Cardiology Clinic, MPC Diabetes and Metabolism Center, Valley Health Center Dermatology/Allergy, Mobile Medical Services, Valley Health Center Pediatrics, Valley Health Center Rheumatology, Valley Health Center Bascom Urgent Care, Valley Health Center OB/GYN, MPC Employee Health/Occupational Medicine, Tully Clinic, OPD-Urgent Care Clinic, Pep Lab, Fair Oaks Community Clinic, Nephrology Clinic, OPD ENT & Eye, OPD Medical Speciality, OPD Surgery, Chaboya Dental Services, OPD Ortho Clinic, MPC Rehab Clinic, Tully Clinic Pharmacy, Homeless Healthcare, In-Service Education—Nursing, and Office of Disaster Medical Supplies, in compliance with Cal. Bus. & Prof. Code §17204 on behalf of itself and on behalf of all other similarly situated counties in California (collectively, the "Counties") who have responsibility for funding public hospitals, and the §340B entities they fund, the affiliated pharmacies, community health centers and/or other public healthcare providers and who, in particular, fund the costs for prescription drugs for the homeless, the disabled, children, and the indigent through the Public Health Service Act of 1992 (the "PHS Act" or "PHS"), §340B Drug Discount Program (the "§340B Program") (42 U.S.C. §256b). This action alleges that the County of Santa Clara, a public entity which owns, operates and provides health services by and through the Santa Clara Valley Health and

Hospital System, and the subdivisions/clinics identified above and all similarly situated counties and the §340B entities they fund, were overcharged for prescription and over-the-counter drugs and pharmaceutical products ("drugs") under the §340B Program pursuant to the PHS Act.

2. In 1992, through enactment of the PHS Act, 42 U.S.C. §256b, Congress established the §340B Program as a condition for participation in Medicaid. The PHS Act requires pharmaceutical manufacturers to provide a statutorily defined discount on outpatient drugs to qualified entities, thereby allowing those healthcare providers, public hospitals, community health centers and other qualified entities to buy pharmaceuticals for their patients at a reduced rate, typically 20%-35% less than non-covered entities would pay for the same pharmaceuticals. These participating entities ("§340B Participants") spent $3.4 billion on outpatient drugs in calendar year 2003 alone, serving the disadvantaged in need of prescription drugs.

3. The Counties have spent considerable sums for the provision of outpatient pharmaceuticals for their residents. In 2004 alone, the County of Santa Clara spent more than $30 million, funding the purchase of out-patient prescription and over-the-counter drugs on behalf of §340B Participants. During fiscal year 2003, the County of Santa Clara spent approximately $29 million, funding the purchase of prescription and over-the-counter drugs on behalf of §340B Participants. For the first eight months of 2005, the County of Santa Clara expended more than $31 million for purchases of §340B pharmaceuticals and over-the-counter drugs.

4. In March 2003, the United States Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG"), the premier healthcare finance investigatory agency in the country, issued a report entitled "Pharmaceutical Manufacturers Overcharged §340B-Covered Entities." OIG Report No. A-06-01-00060 (the "OIG's 2003 Report"). The OIG's 2003 Report estimated that five pharmaceutical manufacturers overcharged §340B Participants $6.1 million for sales occurring during the one-year period ending September 30, 1999.

5. On June 29, 2004, the OIG issued another report (OIG Report No. 0E1-05-02-00070) (the "OIG's 2004 Report"), concluding that pharmaceutical manufacturers repeatedly caused participants in the §340B Program to overpay for prescription drugs. In particular, the OIG's 2004 Report found that more than 97% of §340B Participants surveyed had paid prices for prescription drugs that exceeded the prices that may lawfully be charged to §340B Participants. The OIG's 2004 Report further found all types of drugs that manufacturers had overcharged §340B Participants, extrapolating from September 2002, a single month of overcharges of $41.1 million, that §340B Participants have overpaid for prescription drugs by nearly $500 million per year. A significant portion of these monies has been wrongfully taken and should be returned to plaintiffs to satisfy the unmet need for critical healthcare services in their communities.

6. Under the §340B Program, §340B Participants are denied access to the prescription drug pricing data necessary to determine the lawful price they are to be charged for the prescription drugs they purchase because of the industry's long-standing insis-

tence that all pricing information, no matter how old, is confidential and proprietary.

7. Based on the OIG's 2003 and 2004 Reports, as well as certain plea agreements involving violation of the Medicaid Best Price Reporting Requirements, plaintiffs are informed and believe that they have overpaid for prescription drugs manufactured and/or sold by defendants.

8. Plaintiffs bring this action in part to obtain an accounting concerning the pricing of defendants' products they purchased so that they may determine the extent to which they overpaid for defendants' products and/or overpaid for distribution of such products. Plaintiffs also assert claims for violation of Cal. Bus. & Prof. Code §§17200, *et seq.*, the Unfair Competition Law (the "UCL"), for violation of the California False Claims Act, Cal. Gov't Code §§12650, *et seq.*, for negligence, for breach of contract, for breach of the covenant of good faith and fair dealing, and for *quantum meruit*.

## JURISDICTION AND VENUE

9. On December 2, 2005, this Court held it had federal question jurisdiction over plaintiff's claims arising under the UCL and the California False Claims Act, Cal. Gov't Code §§12650, *et seq.* Venue is proper in this judicial district pursuant to 28 U.S.C. §1391(b) because a substantial part of the events giving rise to the claims occurred in this district.

## THE PARTIES

### Plaintiffs

10. Plaintiffs include the County of Santa Clara, a public entity which owns, operates and provides health services by and through the Santa Clara

Valley Health and Hospital System ("SCVHHS"), and its various clinics and subdivisions, including the following: Santa Clara Valley Medical Center ("SCVMC"), Surgical Daycare 5 West, Electro Encephalography, Oncology Clinic, Moorpark Clinic Pharmacy, Silver Creek Clinic Pharmacy, Out Patient Clinic Pharmacy, East Valley Clinic Pharmacy, South Valley Clinic Pharmacy, Valley Health Center Clinic Pharmacy, Chronic Peritoneal Dialysis—Home, Renal Dialysis, Emergency Department, East Valley Clinic, South Valley Clinic, Silver Creek Clinic, Valley Health Center Administration, MPC Primary Care, Valley Health Center Cardiology Clinic, MPC Diabetes and Metabolism Center, Valley Health Center Dermatology/Allergy, Mobile Medical Services, Valley Health Center Pediatrics, Valley Health Center Rheumatology, Valley Health Center Bascom Urgent Care, Valley Health Center OB/GYN, MPC Employee Health/Occupational Medicine, Tully Clinic, OPD-Urgent Care Clinic, Pep Lab, Fair Oaks Community Clinic, Nephrology Clinic, OPD ENT & Eye, OPD Medical Speciality, OPD Surgery, Chaboya Dental Services, OPD Ortho Clinic, MPC Rehab Clinic, Tully Clinic Pharmacy, Homeless Healthcare, In-Service Education—Nursing, Office of Disaster Medical Supplies, on behalf of all similarly situated California counties and their county-funded §340B entities.

11. The County of Santa Clara Ordinance Code §A18-1 describes the relationship between Santa Clara County and the Santa Clara Valley Health and Hospital System. The Santa Clara County Ordinance Code §A18, subsections 1, 2 and 4, provide as follows: "There is in the County the Santa Clara Valley Health and Hospital System, hereafter referred to in this chapter as the SCVHHS . . . . There is in the SCVHHS the position of Executive Director. The

Executive Director shall be appointed by and supervised by the County Executive in accordance with the provisions of the County Charter and this Code . . . The Executive Director shall have administrative control over SCVHHS which includes the development and administration of the SCVHHS' budget [and] [t]he Executive Director shall be responsible for . . . the collection of all accounts within SCVHHS."

12. The County of Santa Clara has fiscal responsibility for all of the entities/clinics identified above, including SCVMC, a public disproportionate share hospital covered under the §340B Program, and for all of the pharmacies affiliated therewith. Through the funding of these entities, the County of Santa Clara provides healthcare to the indigent and disadvantaged. Plaintiffs have expended county funds to purchase pharmaceuticals used in the outpatient context from defendants at all relevant times. The County of Santa Clara has suffered an injury in fact and lost money as a result of defendants' unlawful conduct as alleged herein.

13. Under Cal. Welf. & Inst. Code §17000 ("Welfare Code §17000"), the Counties must provide healthcare to their residents as the "provider of last resort" or to assure that residents who cannot get care elsewhere have at least their basic healthcare needs met by the Counties.

14. Individually and/or collectively, plaintiffs have purchased drugs from each of the defendants listed below. Plaintiffs have purchased drugs from each of the manufacturer defendants listed below and through defendant Cardinal Health.

**Defendants**

15. Defendant AstraZeneca Pharmaceuticals LP is a Delaware corporation, with its principal place of business located at 1800 Concord Pike, Wilmington, Delaware. AstraZeneca Pharmaceuticals LP is owned and controlled by AstraZeneca PLC, a public limited liability company domiciled in the United Kingdom.

16. Defendants Astra USA, Inc., Zeneca Inc., and AstraZeneca Pharmaceuticals LP are collectively referred to as "AstraZeneca." AstraZeneca maintains research, development, and manufacturing facilities worldwide, including in the United States. AstraZeneca reported annual sales of $16.5 billion in 2001, with an operating profit of $4.2 billion. AstraZeneca manufactures and markets several drugs for use in the outpatient setting, including, but not limited to, Zoladex® (goserelin acetate), Nolvadex® (tamoxifen citrate), Tomudex® (ralitrexed), and Diprivian® (propofol).

17. Defendant Aventis Pharmaceuticals Inc. ("Aventis") is a Delaware corporation with its principal place of business located at 300 Somerset Corporate Boulevard, Bridgewater, New Jersey. Aventis is a wholly owned subsidiary of Aventis, S.A., a company domiciled in France. Aventis is comprised of the U.S. commercial operations of predecessor companies Rhone-Poulenc Rorer, S.A. and Hoechst Marion Roussel, Inc. ("Hoechst"). Prior to its acquisition by Aventis, Hoechst was a Delaware corporation with its principal place of business located at 10236 Marion Park Drive, Kansas City, Missouri. Aventis' principal business activities are the discovery, development, manufacture and sale of prescription pharmaceuticals in the areas of cardiology, oncology, infectious diseases, arthritis, allergies and respiratory

disorders, diabetes and central nervous system disorders. Aventis reported U.S. net sales of approximately $5.8 billion in 2001. Aventis is one of the manufacturers that has overcharged §340B Participants according to the OIG's 2003 Report.

18. The drugs manufactured by Aventis, Hoechst and defendant ZLB Behring LLC (collectively, the "Aventis Group") are used in the outpatient setting and may include, but are not limited to, Anzemet® (dolasetron mesylate), Bioclate® (antihemo factor viii), Gammar® (immune globulin), Helixate® (antihemo factor viii), Humate-P® (antihemo factor viii), Mononine® (antihemo factor ix complex), Monoclate-P® (antihemo factor viii), and Taxotere® (docetaxel).

19. Defendant Bayer Corporation ("Bayer") markets and distributes some 10,000 products in the United States and California. Bayer is headquartered in Pittsburgh, Pennsylvania. Bayer is in the business of developing, manufacturing and marketing pharmaceuticals and other products throughout the United States, including, but not limited to, Viadur® (leuprolide acetate implant), Avelox® (moxifloxacin hydrochloride), Koate®-DVI, Precose® (acarbose), Trasylol® (aprotinin), Adalat CC® (nifedipine), Cipro® (ciprofloxacin HCI), Nimotop® (nimodipine), Prolastin®, Gamimunet® N, Adalat® (nifedipine) Biltricide® (praziquantel), Mycelex® (clotrimazole), Otic Domeboro® (2% acetic acid-aluminum [modified Burrow's]), DTIC-Dome® (dacarbazine), and Tridesilon® (desonide).

20. Defendant Bristol-Myers Squibb Company ("Bristol") is headquartered at 345 Park Avenue, New York, New York. Bristol is in the business of researching, developing, manufacturing and distributing pharmaceuticals and over-the-counter products.

Pharmaceuticals manufactured by Bristol include, but are not limited to, Abilify® (aripiprazole), Avapro® (irbesartan), Cardiolite® (kit for the preparation of Technetium Tc99m Sestamibi for injection), ConvaTec Ostomy Care, ConvaTec Wound Therapeutics, Enfamil® (infant formula), Erbitux® (Cetuixmab), Excedrin® (headache and migraine), Plavix® (ciopidogrel bisulfate), Pravachol® (pravastatin sodium tablets), Reyataz® (atazanavir sulfate), Sustiva® (efavirenz), TAXOL® (paclitaxel injection), Vides® EC (didanosine, delayed-release capsules), Zepcor® (simvastin) and Zerit® (stavudine). Bristol is one of the manufacturers that has overcharged §340B Participants that is the subject of the OIG's 2003 Report.

21. Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline (collectively, "Glaxo") is organized under the laws of Pennsylvania, and is located at One Franklin Plaza, Philadelphia, Pennsylvania. Glaxo controls 45% of the AIDS (Acquired Immune Deficiency Syndrome) drug market. Glaxo also manufactures and markets numerous prescription drugs, including, but not limited to, Augmentin® (amoxicillin/clavolanate potassium), Flonase® (fluticasome propionate), Emitrex®, Paxil® (paroxetine hydrochloride), Wellbutrin (bupropion hydrochloride), Zantac® (ranitidine hydrochloride), Zyban Contac® (bupropion hydrycholoride), Geritol®, Nicoderm CQ®, Nytol®, Sominex®, Tagamet® (cimetidine hyrochloride), and Tums®, as well as other drugs used to treat AIDS patients in the outpatient setting. Glaxo has been identified in the OIG's 2003 Report as one of the manufacturers that has overcharged §340B Participants.

22. Defendant Pfizer Inc. ("Pfizer") is a Delaware corporation with its principal place of business at 235 East 42nd Street, New York, New York. Pfizer is one of the largest pharmaceutical companies in the United States, whether measured by number of prescriptions written, revenues, or market capitalization. Pfizer is in the business of manufacturing and distributing prescription pharmaceuticals for use in the outpatient setting by providers nationwide. Pharmaceuticals that are manufactured by Pfizer and used in an outpatient setting include, but are not limited to, Cerebyx® (fosphenytoin sodium injection), Dilatin® (phenytoin), Difiucan® (fluconazole), Zithromax® (azithromycin), Trovan® (trovafioxacin mesylate), and Unasyn® (ampicillin sodium/sulbactam sodium). Pfizer is also named herein for drugs manufactured by Warner-Lambert Company which it acquired in 2000.

23. Defendant Schering-Plough Corporation ("Schering-Plough") is a New Jersey corporation with its principal place of business located at 2000 Galloping Hill Road, Kenilworth, New Jersey. Schering-Plough's primary business involves prescription products in core product categories, including allergy and respiratory, anti-infective and anticancer, cardiovasculars, dermatologicals and central nervous systems and other disorders. Schering-Plough's revenues in 2001 totaled $9.8 billion.

24. Defendant TAP Pharmaceutical Products Inc. ("TAP") is located at 675 North Field Drive, Lake Forest, Illinois. TAP was formed in 1977 as a joint venture between Abbott Laboratories and Japanese-based Takeda Pharmaceutical Company Limited. TAP develops, markets and sells prescription drugs that are used in the outpatient setting, including

Lupron Depot® (leuprolide acetate for depot suspension) and Prevacid® (lansoprazole), which is sold alone and in dosing packages known as Prevpac® (lansoprazole, amoxicillin and clarithromycin) and Prevacid® NapraPAC™ (lansoprazole and naproxen). TAP has been identified in the OIG's 2003 Report as one of the manufacturers that has overcharged §340B Participants.

25. Defendant Wyeth, Inc. and Wyeth Pharmaceuticals Inc. (collectively, "Wyeth") are Delaware corporations. Wyeth Pharmaceuticals Inc. is headquartered at 500 Arcola Road, Collegeville, Pennsylvania, and is a division of Wyeth Inc., which is headquartered at Five Giralda Farms, Madison, New Jersey. According to its own literature, Wyeth is a global leader in pharmaceuticals. Wyeth is in the business of manufacturing and distributing prescription drugs that are used in outpatient settings. The drugs manufactured by Wyeth that may be used in an outpatient setting include, but are not limited to, Effexor® (venlafaxine), Protonix® (pantoprazole sodium), Benefix® (coagalin factor IX) (recombinent), Zosyn® (piperacillin and tazobactam), Mylotarg® (gemtuzumab ozogamicin), Rapamune® (sirolimus), and Hibtiter® (dipthria CRM protein conjugate).

26. Defendant AmerisourceBergen Corporation ("AmerisourceBergen") is a Delaware corporation, which is located at 1300 Morris Drive, Chesterbrook, Pennsylvania. AmerisourceBergen distributes pharmaceuticals throughout the United States and California, including drugs used in the outpatient settings that are manufactured by some or all of the manufacturer defendants. AmerisourceBergen has been a prime vendor for the sale and distribution of

drugs in California under the §340B Program during the statutory period.

27. Defendant Cardinal Health is an Ohio corporation, which is headquartered at 7000 Cardinal Place, Dublin, Ohio. Cardinal Health distributes pharmaceuticals nationwide and in California, including drugs manufactured by some or all of the manufacturer defendants that are used in the out-patient settings. Cardinal Health has served as a prime vendor for the sale and distribution of drugs in California under the §340B Program during the statutory period. Cardinal Health represents on its website that in addition to distributing drugs, it also provides services, including, but not limited to, drug development, medical products manufacturing, hospital pharmacy consulting and management, and clinical information management.

28. Defendant McKesson Corporation ("McKesson") is a Delaware corporation, located at One Post Street, San Francisco, California. McKesson distributes approximately one third of pharmaceuticals sold in the United States. McKesson distributes drugs used in the outpatient settings pursuant to the §340B Program, including drugs manufactured by some or all of the manufacturer defendants to California counties.

29. Defendant HealthCare Purchasing Partners International, LLC ("HPPI") is a Delaware limited liability company, which is located in Irving, Texas. HPPI is owned by VHA, Inc., which is headquartered in Irving, Texas, and the University HealthSystem Consortium (UHC), located in Oak Brook, Illinois. HPPI is a group purchasing organization offering drug purchasing services pursuant to the §340B Program to more than the 8,000 healthcare organizations

and companies nationwide, including class members. HPPI is the current prime vendor by virtue of government-awarded contract and distributes drugs used in the outpatient settings pursuant to the §340B Program, including drugs manufactured by some or all of the manufacturer defendants.

30. Plaintiffs are informed and believe and thereon allege that each of the named defendants, including those defendants named as Doe defendants, acted as the agent, employee, representative partner, joint venture or co-conspirators of each of the other named defendants in the commission of the acts and omissions alleged herein, and acted within the course and scope of his, her or its duty as such agent, employee, representative, partner, joint venture or co-conspirator. The acts of each such defendant were authorized and/or ratified by each other defendant, and together constitute a single and continuing course of conduct.

## FACTUAL BACKGROUND

### The Section 340B Program

31. In 1992, through enactment of §340B of the PHS Act, 42 U.S.C. §256b, Congress established the §340B Program. The purpose of the §340B Program was to reduce drug prices used in the outpatient context for public hospitals, community health centers and other entities that provide healthcare to the homeless, the disabled, children, and the indigent. These providers are referred to as "§340B Participants."

32. To reduce prescription drug prices for §340B Participants, §340B requires pharmaceutical manufacturers to ensure that §340B Participants pay no more than the "ceiling price," a discounted price

compared to the average manufacturers' price, for any pharmaceutical product. Congress intended that savings be achieved by requiring pharmaceutical manufacturers to give §340B Participants the "best price" for both prescription and over-the-counter drugs to help "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384, 102d Cong., pt. 2, at 12 (2d Sess. 1992). The §340B Program requires the establishment of a prime vendor program, under which the §340B Participants enter into contracts for the distribution of covered outpatient drugs. Manufacturers are responsible for distribution costs whenever a §340B Participant purchases its drugs directly.

33. The §340B Program has become a critical mechanism to serve the healthcare needs of the disadvantaged in their communities through safety net organizations. In calendar year 2003, more than 10,500 eligible healthcare providers participated in the §340B Program and paid an estimated $3.4 billion for outpatient drugs. Section 340B Participants rely on the savings promised by participation in the §340B Program to support their public service missions.

**Administration of the Section 340B Program**

34. The §340B Program is overseen by the Health Resources and Services Administration ("HRSA"). HRSA is an agency within HHS. The HRSA maintains programs and services that have the responsibility for safeguarding the health and well-being of millions of Americans. Each year, over 11 million mostly low-income and uninsured patients are treated in HRSA's health centers, and over 27 million

women, infants, children, and adolescents are served in its maternal and child health programs.

35. Immediate responsibility for oversight of the §340B Program resides in HRSA's Office of Pharmacy Affairs ("OPA"). OPA administers the Pharmaceutical Pricing Agreement ("PPA") signed by drug manufacturers pursuant to §340B who participate in the §340B Program. OPA also maintains an electronic database of §340B Participants, and assists in establishing affordable pharmacy services for new and expanding community health centers.

36. The Centers for Medicare and Medicaid Services ("CMS"), another HHS agency, also has responsibility for administration of the §340B Program. Specifically, pursuant to an intra-agency agreement with HRSA, CMS provides drug price calculations to, theoretically, OPA enabling OPA to monitor drug manufacturers' compliance with their obligations to ensure that §340B Participants pay best prices.

37. The Counties bear the ultimate financial responsibility for their residents' healthcare. Under Welfare Code §17000, California counties must either be the healthcare "provider of last resort" or assure that residents who cannot get care elsewhere have, at least, their basic healthcare needs met.

**Terms of Participation in the Section 340B Program**

38. Section 340B requires defendants to participate in the §340B Program as a condition of having their drug charges reimbursed by the Medicaid program. Charges for more than 15% of all prescription drugs sold in the United States are reimbursed by the Medicaid program. All, or virtually all, pharmaceutical manufacturers participate in the §340B Program

and Medicaid, including defendants named in this action.

39. Section 340B further requires defendants to agree to be bound by the PPA in order to participate in the §340B Program. The PPA sets forth, among other things, the terms and conditions of the defendants' participation in the §340B Program and their obligations to the §340B Participants.

40. Under both §340B and the PPA, defendants are required to ensure that the §340B Participants, the beneficiaries of §340B and the PPA, pay no more for any product than the §340B ceiling price. The §340B ceiling price is based on drug cost data generated by pharmaceutical manufacturers pursuant to the Medicaid Drug Rebate Statute, 42 U.S.C. §1396r-8, particularly the manufacturer's Average Manufacturer Price ("AMP"), a term defined in 42 U.S.C. §1396r-8(k)(1), and the manufacturer's Medicaid rebate amounts based on its lowest selling price, or "best price" as defined in 42 U.S.C. §1396r-8(c)(1)(C). Manufacturers use their ceiling price determinations to establish their §340B price lists.

41. Under the PPA, the manufacturers also are responsible for ensuring that the prices paid for drugs by §340B Participants are at or below the §340B ceiling price, regardless of whether a §340B Participant purchases from a wholesaler or directly from the manufacturer.

42. The PPA also imposes on manufacturers the responsibility to review each quarter the electronic database maintained by OPA of all §340B Participants to determine which community healthcare providers are participating in the §340B Program. This requirement underscores the duty pharmaceutical

manufacturers have to ensure that §340B Participants pay at or below the §340B ceiling price for their pharmaceutical products.

43. The express and essential purpose of §340B and the PPA is to provide §340B Participants with a discounted price from the AMP, known as the "ceiling" or "best" price. The ceiling price is determined in part from the "best" price by which the manufacturer sells the drug to any private purchaser.

44. Plaintiffs and all similarly situated counties relied on defendants' duty to comply with §340B, and on their performance under the PPA, of which plaintiffs are the intended beneficiaries, to ensure that the prices plaintiffs paid for drugs did not exceed the §340B ceiling prices.

45. Plaintiffs believe that they have paid and continue to pay more than the §340B ceiling prices for outpatient drugs manufactured and/or distributed by defendants. Fed. R. Civ. P. 9(b) pleading requirements are relaxed when the facts necessary to plead with specificity are under the exclusive control of defendants, as is the case here. The data necessary to identify the overpayments for §340B drugs is under the exclusive control of defendants, including, but not limited to, the data underlying the AMP, the best price and the §340B ceiling price calculations. Indeed, the OIG confirmed that participating entities cannot verify that they receive the §340B ceiling price due to confidentiality provisions in the authorizing statute.

**Plaintiffs Purchase Significant Quantities of Section 340B Drugs**

46. Plaintiffs have purchased thousands of covered drugs pursuant to the §340B Program from defendants,

including, but not limited to, purchases listed in the attached Exhibit A. Exhibit A lists the names, quantities and prices of drugs plaintiffs purchased from defendants during sample three-month periods.[1] Between 2001 and 2005, plaintiffs purchased significant quantities of multiple drugs pursuant to the §340B Program, including, but not limited to, the following:

(a) **AstraZeneca** — Accolate® Nexium®, Prilosec®, Pulmicort Respules®, Seroquel®, Toprol-XL®, Xylocaine®, and Zomig®;

(b) **Aventis** — Allegra®, Arava®, DDAVP®, Lantus®, Lovenox®, and Taxotere®;

(c) **Bayer** — Ascensia®, Avelox®, Cipro®, and Precose®;

(d) **ZLB Behring LLC** — Stimate®;

(e) **Bristol** — Abilify®, Buspar®, Coumadin®, Cytoxan®, Dovonex®, Glucophage®, Kenalog®, Lac-Hydrin®, Monopril®, Nefazodone®, Plavix®, Pravachol®, Reyataz®, Sustiva®, Trazadone®, Videx®, and Zerit®;

(f) **Glaxo** — Advair Discus®, Augmentin®, Avandia®, Avodart®, Bactroban®, Beconase®, Combivir®, Compazine®, Coreg®, Daraprim®, Dexedrine®, Epivir®, Eskalith®, Flonase®, Flovent Inhalers®, Gaviscon®, Geritol® Hycamtin®, Imitrex, Lamictal®, Lanoxin®, Lexiva®, Mepron®, Navelbine®, Nicoderm®,

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[1] Exhibit A includes sample pricing information for up to three months for each drug listed. The quantities plaintiffs purchased are not limited to those identified in Exhibit A. Plaintiffs also purchased most of the drugs listed in Exhibit A in significant quantities in the months and years preceding and following the time periods identified in Exhibit A.

Paxil® Retrovir®, Serevent®, Timentin®, Trizivir®, Ventolin®, Wellbutrin®, Zantac®, Ziagen®, Zofran®, and Zyban®;

(g) **Pfizer** — Aromasin®, Bextra®, Camptosar®, Celebrex®, Cleocin®, Colestid®, Cortef®, Depo-Provera®, Depo-Testost®, Detrol®, Diflucan®, Dilantin®, Gabapentin, Lipitor®, Neurontin®. Nitrostat®, Norvasc®, Procardia®, Viagra®, Viracept®, Xalatan®, Ziprasidone®, Zithromax®, Zoloft®, and Zyrtec®;

(h) **Schering-Plough** — Avelox®, Cipro®, Claritin®, Lotrimin®, Nasonex®, Peg-Intron®, Proventil®, Rebetol®, and Zetia®;

(i) **TAP** –- Lupron® and Prevacid®; and

(j) **Wyeth** — Alesse®, Centrum®, Dimetapp®, Effexor® (Venlafaxine), Phenergan®, Premarin®, Prempro®, Protonix®, Robitussin®, Triphasil®, and Zosyn®.

**Non-Disclosure of Ceiling Price Data**

47. Defendants have long asserted that their cost and pricing data, no matter how old, is proprietary business information and must be kept confidential. As a result, defendants refuse to disclose their cost and pricing information to purchasers including §340B Participants, or to the prime vendor HPPI, even when the prices the purchasers are required to pay for the manufacturers' products are expressly derived from this data.

48. Defendants' concealment and failure to disclose accurate cost and pricing information that is the basis for their §340B ceiling prices prevented plaintiffs from filing this action earlier.

49. Pursuant to the Medicaid Drug Rebate Statute, CMS receives the pharmaceutical manufacturers' AMP and "best" pricing data, but maintains the data as confidential and does not disclose it to §340B Participants. 42 U.S.C. §1396r-8(b)(3)(D).

50. Based on the AMP and "best price" data CMS receives, pursuant to an intra-agency agreement with HRSA, CMS calculates §340B ceiling prices and provides them to OPA. OPA, however, does not have the resources to conduct audits of the manufacturers' prices to ensure that drug manufacturers' charges to §340B Participants do not exceed the §340B ceiling prices. OPA does not have the program, technology, or staff to match its ceiling price data to the manufacturers' data or in any way to verify the propriety of the prices the §340B Participants pay. Defendants know, or have reason to know, that OPA conducts inadequate or no monitoring of their §340B prices.

51. Pursuant to the PPA, OPA may initiate a process to resolve disputes between the manufacturers and the §340B Participants. OPA may also terminate a drug manufacturer from the §340B Program for violation of the PPA. To date, OPA has never initiated the dispute resolution process or otherwise sought to invoke any of the remedies set forth in the PPA. Neither HRSA nor OPA has the power or authority to impose consequences for violation of §340B on pharmaceutical manufacturers. Hence, exhaustion of any requirement found in the PPA or under the OPA dispute resolution process is, and will continue to be, futile.

52. Government agencies do not have the ability to effectively oversee the prime vendor program. According to the October 2005 OIG Report, entitled

"Deficiencies in the Oversight of the §340B Drug Pricing Program," because the government does not have access to the ceiling price it cannot give the ceiling price to the prime vendor, who then cannot perform its assigned role of negotiating discounts below the ceiling price. Yet, the current prime vendor represents that it is indeed performing such negotiations. As stated on its website (http://www.340bpvp.com/about/), the §340B Prime Vendor Program is managed by HPPI through a contract awarded by the HRSA, the federal agency within HHS responsible for administering the §340B Drug Discount Program, OPA. As to the §340B Prime Vendor, HPPI is responsible for the negotiation of pharmaceutical pricing below the §340B price as well as improving access to affordable medications by establishing a distribution network for pharmaceuticals to covered entities. Participation in the prime vendor program under §340B is entirely voluntarily. Section 340B covered entities are free to purchase drugs from wholesalers other than the prime vendor.

**Section 340B Participants Cannot Obtain Prescription Drug Cost Data Without Judicial Assistance**

53. Plaintiffs do not possess and cannot without Court order obtain the information necessary to verify that the prices the Counties pay for prescription drugs are at or below the §340B ceiling price. Nor can they compel OPA to initiate action.

54. Defendants fraudulently concealed and failed to disclose the facts that they charged plaintiffs more than the best price as required under 42 U.S.C. §256b(a)(1). Plaintiffs did not and could not reasonably discover these facts until, at the earliest, the date upon which the OIG Report was issued in 2003.

55. Plaintiffs have relied on the defendants' compliance with §340B and the PPA to ensure that they pay no more than the ceiling price for any pharmaceutical product than any other private purchaser of that product.

**The OIG Reports Reveal that Section 340B Participants Are Systemically Overpaying for Drugs**

56. In March 2003, the OIG issued a report entitled "Pharmaceutical Manufacturers Overcharged §340B-Covered Entities." OIG's 2003 Report. The report estimates that five pharmaceutical manufacturers (two of which have now merged) overcharged §340B Participants $6.1 million for sales occurring during the one-year period ending September 30, 1999. Those manufacturers are now conducting business as defendants here: Aventis, Bristol, Glaxo and TAP.

57. Similarly, on June 29, 2004, the OIG issued a report entitled "Appropriateness of §340B Drug Prices." OIG's 2004 Report. The OIG's 2004 Report was based on an investigation and analysis of prices paid for drugs by §340B Participants in a single month, September 2002. The OIG's 2004 Report concluded that §340B Participants were repeatedly and widely overcharged for the pharmaceutical manufacturers' products they purchased. Specifically, for September 2002 alone, the month of the sample, the OIG's 2004 Report reported that:

- 31% of sampled drugs purchased by §340B Participants exceeded the §340B ceiling price.
- Section 340B Participants overpaid an estimated $41.1 million on drug expenditures of $269 million.

- 36 of the 37 §340B Participants whose purchases were sampled—more than 97%—paid more than the ceiling price for the prescription drugs they purchased.
- 53% of the drugs sampled exceeded the ceiling price at least once.
- Overcharges were not limited to one or a few manufacturers, but occurred in the products of many manufacturers.

58. The overcharges identified by the OIG's 2004 Report, calculated on an annualized basis, are equal to nearly $500 million per year. The upper range estimate in the OIG's 2004 Report indicates that overcharges may be as high as $259 million per month. The OIG's 2004 Report concluded that "[s]uch a significant overpayment [by §340B Participants] undermines the intent of the 340B program. The $41.1 million overcharged for this 1 month might instead be used to lower the cost of acquiring outpatient drugs so that covered entities can serve more patients and improve the quality of service."

59. On June 29, 2004, the OIG issued a second report entitled "Deficiencies in the 340B Drug Discount Program's Database." OIG Report No. OEI-05-02-00071. In that report, the OIG found that the poor quality of OPA's drug price database prevents OPA from effectively monitoring pharmaceutical product pricing and compliance with §340B requirements.

60. In commenting on the database report, HRSA concurred with the OIG's identification of deficiencies in the §340B database, but said it would be impossible for HRSA to "commit to a timetable" to correct the deficiencies because of "budgetary limitations."

61. As alleged above, plaintiffs are informed and believe that neither OPA nor HRSA has instituted that process because neither HRSA, nor any other entity, has the power to impose consequences for violating the §340B Program. Based on the OIG reports, HRSA's response, OPA's lack of resources, and OPA's failure to exercise any dispute resolution process or enforcement powers in the past, it is virtually certain that OPA will continue to take no action to prevent future overcharges or recover for the §340B Participants for past ones. Manufacturer Audit Guidelines, 59 Fed. Reg. 30,022 (June 10, 1994). As Senator Charles E. Grassley, the Chairman of the Senate Finance Committee, noted in a letter to the HRSA on September 1, 2005, attached as Exhibit B, the lack of oversight and failure to exercise control is a "systemic issue" that must be addressed. OPA will not institute that process because HRSA does not have authority to impose any consequences for violation of the §340B Program.

62. Other federal litigation against the pharmaceutical manufacturers is pending in the United States District Court for the Middle District of Alabama, styled *Central Alabama Comprehensive Healthcare, Inc. y Aventis Pharmaceutical, Inc.*, Case No. 3:04-CV-00673-MHT-VPM (M.D. Ala. July 13, 2004) (the "Alabama action"). That action alleges that the drug manufacturers violated the express terms of §340B and demands an accounting from every defendant to determine whether the prices that a plaintiff paid for defendants' products exceeded the prices permitted under §340B and the PPA, and to what extent.

63. On October 21, 2004, the OIG issued a notice relating to the OIG's 2004 Report that disclosed

enormous overcharges for the single, sampled month of September 2005. On the day it was issued, in a highly unusual move, the notice was presented to the federal court in the Alabama action. The notice represented that the OIG's 2004 Report had suddenly been "withdrawn," that the OIG was reanalyzing some of the data from the OIG's 2004 Report and that it would reissue the report with revisions (when and if it became necessary to do so). Plaintiffs are informed and believe that the data that the OIG states it will reanalyze is not material to the OIG's 2004 Report's essential conclusions. The notice stated that the data it was reanalyzing was put at issue by industry representatives and only "potentially" created a discrepancy that would affect only a small subset of the data. Plaintiffs are informed and believe that even if the data the drug industry representatives have called into question is not accurate, any inaccuracy would not materially affect the conclusions of the OIG's 2004 Report. Moreover, the October 21, 2004 notice withdrawing the OIG's 2004 Report, itself, concluded that:

> Despite our withdrawal of the Report because of problems with the underlying data, we continue to believe that there are systemic issues that lead to price discrepancies within the 340B Drug Pricing Program. ***These newly-discovered data problems do not affect the validity of three findings of the Report. First, we found weaknesses in HRSA's oversight of the Program in that it has no process in place to confirm that §340B entities receive the ceiling price. Second, we found that participating entities cannot independently verify that they receive the 340B ceiling price due to confidentiality provisions in the authorizing***

> ***statute. Finally, we found that pharmaceutical manufacturers' 340B ceiling price calculations are not verified against the Department's calculations of the 340B ceiling price.*** In fact, pharmaceutical manufacturers are not required to and do not report their ceiling prices to the Department . . . .

Plaintiffs are informed and believe that the OIG's unprecedented action, delivering the October 21, 2004 notice immediately to the court upon its issuance that purported to "withdraw" the OIG's 2004 Report, was a result of pressure from the pharmaceutical industry. The October notice from the OIG delivered immediately to the court did not discuss or in any way invalidate any other reports issued by the OIG, including the OIG's 2003 Report.

64. In December 2005, the OIG announced that it expects to release a report in the spring of 2006 that will examine the prices charged to §340B Participants and industry overcharges.

65. On December 15, 2005, a Congressional Subcommittee raised serious concerns over HRSA's oversight of the §340B Program. The hearing, held before the House Energy and Commerce Subcommittee on Oversight and Investigations, focused to a large degree on the need for transparency of the manufacturer defendants' ceiling price information and HHS' authority to ensure compliance with the §340B Program.

**Certain Defendants' Public Admission of Violations of Section 340B Requirements**

66. Under the Medicaid Drug Rebate Statute, drug manufacturers are required to report their "best prices" to the federal government and to pay quar-

terly rebates to Medicaid to ensure that the nation's insurance program for the indigent received the benefit of favorable drug prices offered to other large purchasers of drugs. As a participant in the Medicaid Rebate Program, Schering-Plough was required to report its "best price" for and to pay rebates on Claritin® (loratadine). Similarly, under the provisions of the PHS drug pricing programs, Schering-Plough was required to charge the PHS entities such as AIDS drug programs and community health centers a discounted price, based in part on the Medicaid price. Schering-Plough did not report and change the best price as required. As a result, plaintiffs did not receive the appropriate §340B price.

67. On June 20, 2003, AstraZeneca pled guilty and agreed to pay $355 million in fines for violating the best price requirements with respect to the sale of Zoladex®, a drug used to treat prostate cancer.

68. On October 28, 2002, Pfizer agreed to pay $9 million to settle allegations that it violated the Medicaid Rebate Program.

69. On October 3, 2001, TAP agreed to pay $875 million in fines, of which $559,483,560 was attributed to violation of best price reporting.

70. In each of the foregoing instances, plaintiffs purchased drugs from each of these defendants, and as a result of best price violations, were not charged the correct §340B ceiling price. The information necessary for plaintiffs to determine the exact amount overpaid is currently under the exclusive control of defendants.

71. Based on the facts found and reported in the OIG reports and the defendants' guilty pleas alleged above, Congressional suspicion of wrongdoing and

other evidence that will be presented at trial, it is virtually certain that plaintiffs overpaid for drugs supplied by defendants.

## CLASS ACTION ALLEGATIONS

72. Plaintiffs bring this action on their own behalf and on behalf of all other similarly situated class members, pursuant to the provisions of Cal. Civ. Proc. Code §382 and Cal. Civ. Code §1781. The Class the plaintiffs seek to represent is defined as:

> All California counties who fund participants in the §340B Drug Discount Program, and the §340B participants funded by them under the Public Health Service Act of 1992, who were overcharged by the defendants for drugs and other pharmaceutical products used in the out-patient context.

73. Numerosity of the Class: The Class is composed potentially of as many as 58 counties, the joinder of which in one action would be impracticable. The disposition of their claims through this class action will benefit both the parties and the Court. The identities of Class members are readily ascertainable.

74. Existence and Predominance of Common Questions of Fact and Law: There is a well-defined community of interest in the questions of law and fact involved affecting the members of the Class. The questions of law and fact common to the Class predominate over questions affecting only individual Class members, and include, but are not limited to, the following:

(a) Whether the ceiling price for drugs sold by defendants was the best price;

(b) Whether plaintiffs are entitled to an accounting disclosure by defendants;

(c) Whether defendants overcharged plaintiffs for drugs used in the outpatient context;

(d) Whether plaintiffs and the Class members are entitled to restitution of all overcharged amounts acquired by defendants;

(e) Whether plaintiffs and the Class members are entitled to disgorgement of all profits defendants have collected as a result of the overcharges;

(f) Whether plaintiffs and the Class members are entitled to recover compensatory and punitive damages as a result of defendants' conduct;

(g) Whether plaintiffs and the Class members are entitled to an award of reasonable attorneys' fees, pre-judgment interest, and costs of this suit; and

(h) Whether plaintiffs and the Class members are entitled to injunctive relief.

75. Typicality: Plaintiffs are asserting claims that are typical of the Class, who were forced to bear overcharges by defendants, and have lost money as a result. Plaintiffs and all Class members have similarly suffered harm arising from defendants' violations of the law, as alleged herein.

76. Adequacy: Plaintiffs are adequate representatives of the Class because their interests do not conflict with the interests of the Class members they seek to represent. Plaintiffs will fairly and adequately represent and protect the interests of the Class because they are not antagonistic to the Class. Plaintiffs have retained counsel who are competent and experienced in the prosecution of class action litigation.

77. Superiority: A class action is superior to other available means for the fair and efficient adjudication of plaintiffs' and Class members' claims. Plaintiffs and members of the Class have suffered irreparable harm as a result of defendants' unfair, unlawful, and unconscionable conduct. Absent this action, the Class members will continue to suffer losses, the violations of law described herein will continue without remedy, and defendants will be permitted to retain the proceeds of their misdeeds. Defendants continue to engage in the unlawful, unfair, and unconscionable conduct that is the subject of this Complaint.

## FIRST CAUSE OF ACTION

### For an Accounting Disclosure

78. Plaintiffs hereby repeat, reallege, and incorporate by reference the preceding paragraphs and allegations as if they were fully set forth herein.

79. Pursuant to §340B of the PHS Act and the PPA, each defendant was required by law and agreed to act in good faith and ensure that the price paid for drugs by §340B Participants was at or below the §340B ceiling price, regardless of whether the §340B Participants purchased manufacturers' products through a wholesaler or from a defendant directly. Because defendants refuse to disclose the actual §340B ceiling prices, and the cost data is in their exclusive possession, plaintiffs were forced to repose a confidence in the defendants and rely and trust in the integrity of the defendants to charge prices at or below the §340B ceiling prices.

80. Plaintiffs are the intended beneficiaries of the protections established by §340B and the intended third-party beneficiaries of the PPA.

81. Plaintiffs are informed and believe that they were charged significantly more than the §340B ceiling price on a substantial number of prescription drugs purchased by participating §340B entities, including SCVMC, its pharmacy, and other county pharmacies.

82. As a result of their failure to ensure that the prices paid by plaintiffs and the Class members for defendants' products were at or below the §340B ceiling price, defendants have breached a fiduciary duty and taken unfair advantage of the confidence imposed on them by depriving plaintiffs and the Class members of the benefits they are entitled to under §340B and the PPA.

83. Plaintiffs are without an administrative remedy and without effective administrative protection of their interests.

84. Plaintiffs are entitled to an accounting disclosure from each defendant to determine whether the prices they paid for covered outpatient drugs exceeded the price permitted under §340B and the PPA, and to what extent.

## SECOND CAUSE OF ACTION

### For Violation of California Business and Professions Code Sections 17200, *et seq.*

85. Plaintiffs hereby repeat, reallege, and incorporate by reference the preceding paragraphs and allegations as if they were fully set forth herein.

86. Pursuant to §340B of the PHS Act and the PPA, defendants were required by federal law and agreed that the price paid for drugs by §340B Participants would be or was at or below the §340B ceiling price, regardless of whether the §340B Participants pur-

chased manufacturers' products through a distributor or directly from a manufacturer.

87. Plaintiffs are informed and believe and thereon allege that, as described herein, defendants have engaged in an unfair, unlawful, and/or deceptive scheme to collect inflated charges that exceed the §340B ceiling price from plaintiffs. Defendants unfairly, unlawfully and/or fraudulently charged §340B Participants funded by plaintiffs substantially more than the §340B ceiling price on a significant number of prescription drugs purchased through their participation in the §340B Program.

88. Plaintiffs are informed and believe and thereon allege that, as described herein, defendants' conduct constitutes unfair competition within the meaning of Cal. Bus. & Prof. Code §§17200, *et seq.*, as it prohibits "any unlawful, unfair or fraudulent business act or practice" and "unfair, deceptive, untrue or misleading advertising." Cal. Bus. & Prof. Code §17200.

89. The UCL forbids all wrongful business activities in any context. Defendants' practices are unlawful, deceptive, immoral, unethical, oppressive, and unscrupulous, and offend established public policies, and have specifically resulted in injury to plaintiffs and the Class. Plaintiffs have paid more for drugs, both prescription and over-the-counter, than they should have paid pursuant to the PPA. The impact of defendants' practices is in no way mitigated by any justifications, reasons or motives. Defendants' conduct has no utility when compared to the harm to plaintiffs.

90. As a result of the aforementioned conduct in violation of the UCL, plaintiffs are entitled to equitable relief, including restitution of all charges and dis-

gorgement of profits, attorneys' fees and costs, and permanent injunctive relief to prevent such conduct in the future.

**THIRD CAUSE OF ACTION**

**For Violation of California False Claims Act, California Government Code Sections 12650, *et seq.***

91. Plaintiffs hereby repeat, reallege, and incorporate by reference the preceding paragraphs and allegations as if they were fully set forth herein.

92. Throughout the statutory period, and before, defendants, each of them, either independently or in conjunction with one or more other defendants, presented invoices or statements to plaintiffs for payment of §340B drugs manufactured and/or distributed by the defendants, including, but not limited to, §340B drugs identified in the attached Exhibit A and in ¶46 above.

93. Defendants presented false statements to plaintiffs by falsely representing that prices charged, including, but not limited to, those identified in Exhibit A, were below the §340B ceiling price.

94. Defendants have prevented, and continue to prevent, plaintiffs from learning the true §340B ceiling prices for the drugs purchased. Therefore, plaintiffs cannot presently calculate the ceiling prices with specificity or at all because the data necessary to do so continues to be under the exclusive control of defendants. Plaintiffs believe that defendants' pricing data, once obtained, will confirm that defendants charged plaintiffs prices that far exceed the true §340B ceiling prices. Accordingly, plaintiffs allege that each defendant has violated the California False Claims Act, Cal. Gov't Code §12651, by:

(a) Knowingly presenting or causing to be presented to an officer or employee of plaintiffs false claims for payment for prescription and over-the-counter outpatient drugs in the outpatient context (Cal. Gov't Code §12651(a)(1));

(b) Knowingly making, using, or causing to be made a false record or statement to get a false claim paid and/or approved by plaintiffs (Cal. Gov't Code §12651(a)(2));

(c) Knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay money to plaintiffs (Cal. Gov't Code §12651(a)(7)); and/or

(d) Benefiting from the inadvertent submission of a false claim to plaintiffs, subsequently discovering the falsity of the claim and failing to disclose the false claim to plaintiffs within a reasonable time after discovery of the false claim (Cal. Gov't Code §12651 (a)(8)).

95. As a result of the foregoing violations of the California False Claims Act, plaintiffs are entitled to not less than two times, but not more than three times, the amount of damages sustained by each of them, in addition to reasonable costs and attorneys' fees, in addition to any other remedy the Court may deem appropriate.

## FOURTH CAUSE OF ACTION

### For Negligence

96. Plaintiffs hereby repeat, reallege, and incorporate by reference the preceding paragraphs and allegations as if they were fully set forth herein.

97. It was defendants' duty to use due care to ensure that they did not charge plaintiffs prices

above and beyond the §340B ceiling prices mandated by law for the sale of outpatient drugs and products to §340B entities.

98. Defendants breached that duty of due care by failing to use ordinary or reasonable care which persons of ordinary prudence would use under similar circumstances to ensure that plaintiffs received the §340B discounts required by law.

99. As a direct and proximate result of defendants' negligence, plaintiffs have suffered damages representing the difference between the prices paid by plaintiffs for various outpatient drugs and products, and the discounted §340B prices which should have been charged for those outpatient drugs and products.

100. All the above damages were directly and proximately caused by the negligence of defendants and were incurred without contributory negligence or assumption of the risk on the part of plaintiffs. Plaintiffs could not avoid the overcharges for reasons, including, but not limited to, the fact that all of the §340B ceiling price and cost data is in the exclusive possession of defendants.

**FIFTH CAUSE OF ACTION**

**For Breach of Contract**

101. Plaintiffs hereby repeat, reallege, and incorporate by reference the preceding paragraphs and allegations as if they were fully set forth herein.

102. Defendants have agreed to be bound by the PPA, the contract with the Secretary of HHS setting forth the terms of participation in the §340B Program. The PPA expressly reflects the intention of the contracting parties to directly benefit the covered entities, including plaintiffs, by ensuring that the

covered entities as beneficiaries pay no more than the §340B ceiling price for covered drugs. "Pursuant to requirements under section 340B . . . the Manufacturer agrees . . . to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported . . . ."

103. By agreeing to the terms of the PPA with HHS, the defendants expressly agreed to sell covered drugs to the covered entities, including plaintiffs, at below the §340B ceiling price. Defendants breached, and continue to breach, their contractual obligations under the PPA by charging plaintiffs and the Class members more than the §340B ceiling price for covered drugs.

104. As the intended beneficiaries of the PPA, plaintiffs and the Class members are entitled to damages they sustained as a result of defendants' breach of contract, in addition to reasonable costs and attorneys' fees, and other remedies as the Court may deem appropriate.

## SIXTH CAUSE OF ACTION

### For Breach of Covenant of Good Faith and Fair Dealing

105. Plaintiffs hereby repeat, reallege, and incorporate by reference the preceding paragraphs and allegations as if they were fully set forth herein.

106. Defendants agreed to be bound by the PPA, the contract with HHS setting forth the terms of participation in the §340B Program. The PPA expressly reflects the intention of the contracting parties to directly benefit the covered entities, including plaintiffs, by ensuring that the covered entities as benefi-

ciaries pay no more than the §340B ceiling price for covered drugs. "Pursuant to requirements under section 340B . . . the Manufacturer agrees . . . to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported . . . . "

107. By agreeing to the terms of the PPA with HHS, defendants had and continue to have an implied duty of good faith and fair dealing in performing the terms of the PPA.

108. Defendants knowingly breached, and continue to breach, the implied covenant of good faith and fair dealing by failing to perform in good faith the terms of the PPA and failing to ensure that plaintiffs and Class members pay below the §340B ceiling price for covered drugs.

109. As the intended beneficiaries of the PPA, plaintiffs and the Class members are entitled to damages they sustained as a result of defendants' breach of duty of good faith and fair dealing, in addition to reasonable costs and attorneys' fees, and other remedies as the Court may deem appropriate.

## SEVENTH CAUSE OF ACTION

### *Quantum Meruit*

110. Plaintiffs hereby repeat, reallege, and incorporate by reference the preceding paragraphs and allegations as if they were fully set forth herein.

111. Defendants agreed to supply drugs to plaintiffs at prices no greater than the §340B ceiling price. Defendants requested and received payment for §340B drugs from plaintiffs and were thereby unjustly enriched to the degree that the prices exceeded the §340B ceiling prices. Defendants failed and refused to

comply with their obligations and agreements, and as a result, defendants have retained monies to which they are not entitled and that belong to plaintiffs.

112. Plaintiffs and Class members have suffered harm as a proximate result of the violations of law and wrongful conduct of defendants as alleged herein.

113. If defendants are permitted to keep monies collected by their unlawful overcharging to §340B Participants, they will be unjustly enriched at the expense of plaintiffs. As such, plaintiffs are entitled to full restitution.

**PRAYER FOR RELIEF**

WHEREFORE, plaintiffs pray for judgment as follows:

A. Requiring defendants to immediately cease their unlawful acts and practices;

B. Requiring defendants to make full restitution of all monies wrongfully obtained;

C. Requiring defendants to disgorge all ill-gotten revenues and/or profits;

D. Certifying the Class and appointing plaintiffs their undersigned counsel of record to represent the Class, with respect to the first, second and fourth causes of action set forth herein;

E. Requiring defendants to provide an accounting of the §340B ceiling prices for all products in all package sizes for all months or quarters in which plaintiffs purchased such products through their §340B Participants;

F. Granting appropriate injunctive relief pursuant to all causes of action to prevent the practices alleged herein from continuing;

G. Awarding plaintiffs damages to the full extent of the law, including double or triple damages, and/or punitive damages where appropriate;

H. Imposing a constructive trust and ordering defendants to pay restitution to plaintiffs and the Class members in the amount they have been overcharged for drugs they purchased for §340B Participants from defendants, with interest;

I. Awarding plaintiffs the fees and expenses incurred in this action, including reasonable allowance of fees for plaintiffs' attorneys and experts; and

J. Granting plaintiffs such other and further relief as the Court may deem just and proper.

**JURY DEMAND**

Plaintiffs hereby demand a trial by jury of all issues so triable.

DATED: February 28, 2006

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# REBATE AGREEMENT

Between

The Secretary of Health and Human Services (hereinafter referred to as "the Secretary")

and

The Manufacturer Identified in Section XI of this Agreement (hereinafter referred to as "the Labeler")

The Secretary, on behalf of the Department of Health and Human Services and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement) which have a Medicaid State Plan approved under 42 U.S.C. section 1396a, and the Labeler, on its own behalf, for purposes of section 4401 of the Omnibus Budget Reconciliation Act of 1990, Pub. L. No. 101-508, and section 1927 of the Social Security Act (hereinafter referred to as "the Act"), 42 U.S.C. 1396s, hereby agree to the following:

## I DEFINITIONS

The terms defined in this section will, for the purposes of this agreement, have the meanings specified in section 1927 of the Act as interpreted and applied herein:

(a) "Average Manufacturer Price (AMP)" means, with respect to a Covered Outpatient Drug of the Manufacturer for a calendar quarter, the average unit price paid to the Manufacturer for the drug in the States by wholesalers for drugs distributed to the retail pharmacy class of trade (excluding direct sales to hospitals, health maintenance organizations and to wholesalers where the drug is relabeled under that distributor's national drug code number). Federal Supply Schedule prices are not included in the calculation of AMP. AMP includes cash discounts

allowed and all other price reductions (other than rebates under section 1927 of the Act), which reduce the actual price paid. It is calculated as a weighted average of prices for all the Manufacturer's package sizes for each Covered Outpatient Drug sold by the Manufacturer during that quarter. Specifically, it is calculated as Net Sales divided by numbers of units sold, excluding free goods (i.e. drugs or any other items given away, but not contingent on any purchase requirements). For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The Average Manufacturer Price for a quarter must be adjusted by the Manufacturer if cumulative discounts or other arrangements subsequently adjust the prices actually realized.

(b) "Base Consumer Price Index-Urban (CPI-U)" is the CPI-U for September, 1990. For drugs approved by FDA after October 1, 1990, "Base CPI-U" means the CPI-U for the month before the month in which the drug was first marketed.

(c) "Base Date AMP" means the AMP for the 7/1/90-9/30/90 quarter for purposes of computing the AMP as of 10/1/90. For drugs approved by FDA after October 1, 1990, "Base Date AMP" means the AMP for the first day of the first month in which the drug was marketed. In order to meet this definition, the drug must have been marketed on that first day. If the drug was not marketed on that first day, "Base Date" means the AMP for the first day of the month in which the product was marketed for a full month.

(d) "Best Price" means, with respect to Single Source and Innovator Multiple Source Drugs, the lowest price at which the manufacturer sells the Covered Outpatient Drug to any purchaser in the United

States in any pricing structure (including capitated payments), in the same quarter for which the AMP is computed. Best price includes prices to wholesalers, retailers, nonprofit entities, or governmental entities within the States (excluding Depot Prices and Single Award Contract Prices of any agency of the Federal Government). Federal Supply Schedule prices are included in the calculation of the best price.

The best prices shall be inclusive of cash discounts, free goods, volume discounts, and rebates, (other than rebates under Section 1927 of the Act).

It shall be determined on a unit basis without regard to special packaging, labeling or identifiers on the dosage form or product or package, and shall not take into account prices that are Nominal in amount. For Bundled Sales, the allocation of the discount is made proportionately to the dollar value of the units of each drug sold under the bundled arrangement. The best price for a quarter shall be adjusted by the manufacturer if cumulative discounts, rebates or other arrangements subsequently adjust the prices actually realized.

(e) "Bundled Sale" refers to the packaging of drugs of different types where the condition of rebate or discount is that more than one drug type is purchased, or where the resulting discount or rebate is greater than that which would have been received had the drug products been purchased separately.

(f) "Centers for Medicare & Medicaid Services (CMS)" (formerly HCFA) means the agency of the Department of Health and Human Services having the delegated authority to operate the Medicaid Program.

(g) "Consumer Price Index-Urban (CPI-U)" means the index of consumer prices developed and updated by the U.S. Department of Commerce. As referenced in section 1927(c) of the Act, it is the CPI for all urban consumers (U.S. Average) and, except for the base CPI-U, it shall be the index for the month before the beginning of the calendar quarter for which the rebate is made.

(h) "Covered Outpatient Drug" will have the meaning as set forth in Section 1927(k)(2),(k)(3) and (k)(4) of the Act, and with respect to the Manufacturer includes all such drug products meeting this definition. For purposes of coverage under this agreement, all of those Covered Outpatient Drugs are identified by the Manufacturer's labeler code segment of the NDC number. Certain Covered Outpatient Drugs, such as specified by Section 1927 (d) (1) (3) of the Act, may be restricted or excluded from Medicaid payment at State option but shall be included by the Manufacturer for purposes of this agreement.

(i) "Depot Price" means the price(s) available to any depot of the federal government, for purchase of drugs from the Manufacturer through the depot system of procurement.

(j) "Individual State Agreement" means an agreement between a State and a Manufacturer authorized or approved by CMS as meeting the requirements specified in Section 1927(a)(1) or (a)(4) of the Act. Amendments or other changes to agreements under 1927(a)(4) shall not be included in this definition unless specifically accepted by CMS.

An existing agreement that met these requirements as of the date of enactment of P.L. No. 101-508

(November 5, 1990), can be modified to give a greater rebate percentage.

(k) "Innovator Multiple Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(ii) of the Act and shall include all Covered Outpatient Drugs approved under a New Drug Application (NDA), Product License Approval (PLA), Establishment License Approval (ELA) or Antibiotic Drug Approval (ADA). A Covered Outpatient Drug marketed by a cross-licensed producer or distributor under the approved NDA shall be included as an innovator multiple source drug when the drug product meets this definition.

(l) "Manufacturer" will have the meaning set forth in Section 1927(k)(5) of the Act except, for purposes of this agreement, it shall also mean the entity holding legal title to or possession of the NDC number for the Covered Outpatient Drug.

(m) "Marketed" means that a drug was first sold by a manufacturer in the States after FDA approval.

(n) "Medicaid Utilization Information" means the information on the total number of units of each dosage form and strength of the Manufacturer's Covered Outpatient Drugs reimbursed during a quarter under a Medicaid State Plan. This information is based on claims paid by the State Medicaid Agency during a calendar quarter and not drugs that were dispensed during a calendar quarter (except it shall not include drugs dispensed prior to January 1, 1991). The Medicaid Utilization Information to be supplied includes: 1) NDC number; 2) Product name; 3) Units paid for during the quarter by NDC number; 4) Total number of prescriptions paid for during the quarter by NDC number; and 5) Total amount paid

during the quarter by NDC number. A State may, at its option, compute the total rebate anticipated, based on its own records, but it shall remain the responsibility of the labeler to correctly calculate the rebate amount based on its correct determination of AMP and, where applicable, Best Price.

(o) "National Drug Code (NDC)" is the identifying drug number maintained by the Food and Drug Administration (FDA). For the purposes of this agreement the complete 11 digit NDC number will be used including labeler code (which is assigned by the FDA and identifies the establishment), product code (which identifies the specific product or formulation), and package size code. For the purposes of making Rebate Payments, Manufacturers must accept the NDC number without package size code from States that do not maintain their records by complete NDC number.

(p) "Net Sales" means quarterly gross sales revenue less cash discounts allowed and all other price reductions (other than rebates under section 1927 of the Act) which reduce the actual price paid; and as further defined under the definition of AMP.

(q) "New Drug" means a Covered Outpatient Drug approved as a new drug under section 201(p) of the Federal Food, Drug, and Cosmetic Act.

(r) "New Drug Coverage" begins with the date of FDA approval of the NDA, PLA, ELA or ADA, for a period of six months from that date, with the exception of drugs not under the rebate agreement or classes of drugs States elect to exclude.

(s) "Nominal Price", for purposes of excluding prices from the Best Price calculation, means any

price less than 10% of the AMP in the same quarter for which the AMP is computed.

(t) "Noninnovator Multiple Source Drug" shall have the meaning as set forth in Section 1927 (k)(7)(A)(iii) of the Act. It also includes Covered Outpatient Drugs approved under an ANDA or AADA.

(u) "Quarter" means calendar quarter unless otherwise specified.

(v) "Rebate Payment" means, with respect to the Manufacturer's Covered Outpatient Drugs, the quarterly payment by the Manufacturer to the State Medicaid Agency, calculated in accordance with section 1927 of the Act and the provisions of this agreement. The terms "Base CPI-U" and "Base Date AMP" will be applicable to the calculations under 1927(c).

(w) "Secretary" means the Secretary of the United States Department of Health and Human Services, or any successor thereto, or any officer or employee of the Department of Health and Human Services or successor agency to whom the authority to implement this agreement has been delegated.

(x) "Single-Award Contract" means a contract between the Federal Government and a Manufacturer resulting in a single supplier for a Covered Outpatient Drug within a class of drugs. The Federal Supply Schedule is not included in this definition as a single award contract.

(y) "Single-Award Contract Price" means a price established under a Single-Award Contract.

(z) "Single Source Drug" will have the meaning set forth in Section 1927(k)(7)(A)(iv) of the Act. It also

includes a Covered Outpatient Drug approved under a PLA, ELA or ABA.

(aa) "States" means the 50 states and the District of Columbia.

(bb) "State Medicaid Agency" means the agency designated by a State under Section 1902(a)(5) of the Act to administer or supervise the administration of the Medicaid program.

(cc) "Unit" means drug unit in the lowest identifiable amount (e.g. tablet or capsule for solid dosage forms, milliliter for liquid forms, gram for ointments or creams). The Manufacturer will specify the unit associated with each Covered Outpatient Drug, as part of the submission of data, in accordance with the Secretary's instructions provided pursuant to Appendix A.

(dd) "Unit Rebate Amount" means the unit amount computed by the Health Care Financing Administration to which the Medicaid utilization information may be applied by States in invoicing the Manufacturer for the rebate payment due.

(ee) "Wholesaler" means any entity (including a pharmacy or chain of pharmacies) to which the labeler sells the Covered Outpatient Drug, but that does not relabel or repackage the Covered Outpatient Drug.

## II MANUFACTURER'S RESPONSIBILITIES

In order for the Secretary to authorize that a State receive payment for the Manufacturer's drugs under Title XIX of the Act, 42 U.S.C. Section 1396 et seq., the Manufacturer agrees to the following:

(a) To calculate and, except as provided under section V(b) of this agreement, to make a Rebate

Payment to each State Medicaid Agency for the Manufacturer's Covered Outpatient Drugs paid for by the State Medicaid Agency during a quarter.

A separate listing of all Covered Outpatient Drugs and other information, in accordance with CMS's specifications pursuant to Appendix A, must be submitted within 30 calendar days of entering into this agreement and be updated quarterly. The Manufacturer's quarterly report is to include all new NDC numbers and continue to list those NDC numbers for drugs no longer marketed.

(b) Except as provided under V(b), to make such rebate payments for each calendar quarter within 30 days after receiving from the State the Medicaid Utilization Information defined in this agreement. Although a specific amount of information has been defined in I(n) of this agreement, the Manufacturer is responsible for timely payment of the rebate within 30 days of receiving, at a minimum, information on the number of units paid, by NDC number.

(c) To comply with the conditions of 42 U.S.C. section 1396s, changes thereto and implementing regulations as the Secretary deems necessary and specifies by actual prior notice to the manufacturer.

(d) That rebate agreements between the Secretary and the Manufacturer entered into before March 1, 1991 are retroactive to January 1, 1991. Rebate agreements entered into on or after March 1, 1991 shall be effective the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(e) To report to the Secretary, in accordance with specifications pursuant to Appendix A, that information on the Average Manufacturer Price and, in the

case of Single Source and Innovator Multiple Source Drugs, the Manufacturer's Best Price for all Covered Outpatient Drugs. The Manufacturer agrees to provide such information within 30 days of the last day of each quarter beginning with (1) the January 1, 1991-March 31, 1991 quarter or (2) the quarter in which any subsequent effective date of this agreement lies. Other information in Appendix A shall also be required within 30 days of the last day of the quarter. Adjustments to AMP or Best Price for prior quarters shall also be reported on this quarterly basis.

(f) In the case of Single Source and Innovator Multiple Source drugs, to report to the Secretary, in a manner prescribed by the Secretary, the information in Appendix A on the Base Date AMP. The Manufacturer agrees to provide such information within 30 days of the date of signing this agreement.

(g) To directly notify the States of a New Drug's Coverage.

(h) To continue to make a Rebate Payment on all of its Covered Outpatient Drugs for as long as an agreement with the Secretary is in force and State Medicaid Utilization Information reports that payment was made for that drug, regardless of whether the Manufacturer continues to market that drug. If there are no sales by the Manufacturer during a quarter, the AMP and Best Price last reported continue to be used in calculating rebates.

(i) To keep records (written or electronic) of the data and any other material from which the calculations of AMP and Best Price were derived. In the absence of specific guidance in section 1927 of the Act, Federal regulations and the terms of this agreement, the Manufacturer may make reasonable

assumptions in its calculations of AMP and Best Price, consistent with the intent of section 1927 of the Act, Federal regulations and the terms of this agreement. A record (written or electronic) outlining these assumptions must also be maintained.

## III SECRETARY'S RESPONSIBILITIES

(a) The Secretary will use his best efforts to ensure that the State agency will report to the Manufacturer, within 60 days of the last day of each quarter, and in a manner prescribed by the Secretary, Medicaid Utilization Information paid for during the quarter.

(b) The Secretary may survey those Manufacturers and Wholesalers that directly distribute their covered outpatient drugs to verify manufacturer prices and may impose civil monetary penalties as provided in section 1927(b)(3)(B) of the Act and IV of this agreement.

(c) The Secretary may audit Manufacturer calculations of AMP and Best Price.

## IV PENALTY PROVISIONS

(a) The Secretary may impose a civil monetary penalty under III(b), up to $100,000 for each item, on a wholesaler, manufacturer, or direct seller of a Covered Outpatient Drug, if a wholesaler, manufacturer or direct seller of a Covered Outpatient Drug refuses a request for information about charges or prices by the Secretary in connection with a survey or knowingly provides false information. The provisions of section 1128A of the Act (other than subsection (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply as set forth in section 1927(b)(3)(B).

(b) The Secretary may impose a civil monetary penalty, in an amount not to exceed $100,000, for each item of false information as set forth in 1927 (b)(3)(C)(ii).

(c) The Secretary may impose a civil monetary penalty for failure to provide timely information on AMP, Best Price or Base Date AMP. The amount of the penalty shall be increased by $10,000 for each day in which such information has not been provided, as set forth in 1927(b)(3)(C)(i).

V DISPUTE RESOLUTION—MEDICAID UTILIZATION INFORMATION

(a) In the event that in any quarter a discrepancy in Medicaid Utilization Information is discovered by the Manufacturer, which the Manufacturer and the State in good faith are unable to resolve, the Manufacturer will provide written notice of the discrepancy, by NDC number, to the State Medicaid Agency prior to the due date in II(b).

(b) If the Manufacturer in good faith believes the State Medicaid Agency's Medicaid Utilization Information is erroneous, the Manufacturer shall pay the State Medicaid Agency that portion of the rebate amount claimed which is not disputed within the required due date in II (b). The balance due, if any, plus a reasonable rate of interest as set forth in section 1903(d)(5) of the Act, will be paid or credited by the Manufacturer or the State by the due date of the next quarterly payment in II(b) after resolution of the dispute.

(c) The State and the Manufacturer will use their best efforts to resolve the discrepancy within 60 days of receipt of such notification. In the event that the State and the Manufacturer are not able to resolve a

discrepancy within 60 days, CMS shall require the State to make available to the Manufacturer the State hearing mechanism available under the Medicaid Program (42 Code of Federal Regulations section 447.253 (c)).

(d) Nothing in this section shall preclude the right of the Manufacturer to audit the Medicaid Utilization Information reported (or required to be reported) by the State. The Secretary shall encourage the Manufacturer and the State to develop mutually beneficial audit procedures.

(e) Adjustments to Rebate Payments shall be made if information indicates that either Medicaid Utilization Information, AMP or Best Price were greater or less than the amount previously specified.

(f) The State hearing mechanism is not binding on the Secretary for purposes of his authority to implement the civil money penalty provisions of the statute or this agreement.

VI DISPUTE RESOLUTION—PRESCRIPTION DRUGS ACCESS AND STATE SYSTEMS ISSUES

(a) A State's failure to comply with the drug access requirements of section 1927 of the Act shall be cause for the Manufacturer to notify CMS and for CMS to initiate compliance action against the State under section 1904 of the Act. A request for compliance action may also occur when the Manufacturer shows a pattern or history of inaccuracy in Medicaid Utilization Information.

(b) Such compliance action by CMS will not relieve the Manufacturer from its obligation of making the Rebate Payment as provided in section 1927 of the Act and this agreement.

## VII CONFIDENTIALITY PROVISIONS

(a) Pursuant to Section 1927(b)(3)(D) of the Act and this agreement, information disclosed by the Manufacturer in connection with this Agreement is confidential and, not withstanding other laws, will not be disclosed by the Secretary or State Medicaid Agency in a form which reveals the Manufacturer, or prices charged by the Manufacturer, except as necessary by the Secretary to carry out the provisions of section 1927 of the Act, and to permit review under section 1927 of the Act by the Comptroller General.

(b) The Manufacturer will hold State Medicaid Utilization Information confidential. If the Manufacturer audits this information or receives further information on such data, that information shall also be held confidential. Except where otherwise specified in the Act or agreement, the Manufacturer will observe State confidentiality statutes, regulations and other properly promulgated policy.

(c) Notwithstanding the nonrenewal or termination of this Agreement for any reason, these confidentiality provisions will remain in full force and effect.

## VIII NONRENEWAL AND TERMINATION

(a) Unless otherwise terminated by either party pursuant to the terms of this Agreement, the Agreement shall be effective for an initial period of one year beginning on the date specified in section II(d) of this agreement and shall be automatically renewed for additional successive terms of one year unless the Labeler gives written notice of intent not to renew the agreement at least 90 days before the end of the current period.

(b) The Manufacturer may terminate the agreement for any reason, and such termination shall become effective the later of the first day of the first calendar quarter beginning 60 days after the Manufacturer gives written notice requesting termination, or the ending date of the term of the agreement if notice has been given in accordance with VII(a).

(c) The Secretary may terminate the Agreement for violations of this agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause. The Secretary shall provide, upon request, a Manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(d) If this rebate agreement is nonrenewed or terminated, the Manufacturer is prohibited from entering into another rebate agreement as provided in section 1927(b)(4)(C) of the Act until a period of one calendar quarter has elapsed from the effective date of the termination, unless the Secretary finds good cause for earlier reinstatement.

(e) Any nonrenewal or termination will not affect rebates due before the effective date of termination.

## IX GENERAL PROVISIONS

(a) Any notice required to be given pursuant to the terms and provisions of this Agreement will be sent in writing.

Notice to the Secretary will be sent to:

Center for Medicaid and State Operations
Family and Children's Health Programs Group
Division of Benefits, Coverage and Payment
Post Office Box 26686
Baltimore, MD 21207-0486

Notices to CMS concerning data transfer and information systems issues are to be sent to:

Center for Medicaid and State Operations
Finance, Systems and Quality Group
Division of State Systems
Post Office Box 26686
Baltimore, MD 21207-0486

The CMS address may be updated upon written notice to the Manufacturer.

Notice to the Manufacturer will be sent to the address as provided with this agreement and updated upon Manufacturer notification to CMS at the address in this agreement.

(b) In the event of a transfer in ownership of the Manufacturer, this agreement is automatically assigned to the new owner subject to the conditions specified in section 1927 and this agreement.

(c) Nothing in this Agreement will be construed to require or authorize the commission of any act contrary to law. If any provision of this Agreement is found to be invalid by a court of law, this Agreement will be construed in all respects as if any invalid or unenforceable provision were eliminated, and without any effect on any other provision.

(d) Nothing in this Agreement shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or the Secretary under the Constitution, the Act, other federal laws, or State laws.

(e) The rebate agreement shall be construed in accordance with Federal common law and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme.

(f) The terms "State Medicaid Agency" and "Manufacturer" incorporate any contractors which fulfill responsibilities pursuant to the agreement unless specifically provided for in the rebate agreement or specifically agreed to by an appropriate CMS official.

(g) Except for the conditions specified in II(c) and IX(a), this Agreement will not be altered except by an amendment in writing signed by both parties. No person is authorized to alter or vary the terms unless the alteration appears by way of a written amendment, signed by duly appointed representatives of the Secretary and the Manufacturer.

(h) In the event that a due date falls on a weekend or Federal holiday, the report or other item will be due on the first business day following that weekend or Federal holiday.

X APPENDIX

Appendix A attached hereto is part of this agreement.

XI SIGNATURES

FOR THE SECRETARY OF HEALTH AND HUMAN SERVICES

By: _____ _____
Date

Title: Deputy Director
Finance, Systems and Quality Group
Center for Medicaid and State Operations
Centers for Medicare & Medicaid Services
Department of Health and Human Services

ACCEPTED FOR THE MANUFACTURER

I certify that I have made no alterations, amendments or other changes to this rebate agreement.

By:_____ _____

(signature) (please print name)

Title: _____

Name of Manufacturer: _____

Manufacturer Address: _____

Manufacture. Labeler Code(s): _____

Date: _____

# PETITIONER'S BRIEF

Supreme Court, U.S.
FILED
NOV 12 2010
OFFICE OF THE CLERK

No. 09-1273

IN THE

# Supreme Court of the United States

ASTRA USA, INC., *et al.*,
*Petitioners*,

v.

COUNTY OF SANTA CLARA,
ON BEHALF OF ITSELF AND ALL
OTHERS SIMILARLY SITUATED,
*Respondent*.

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

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## QUESTION PRESENTED

Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, imposes ceilings on the prices that drug manufacturers may charge for prescription medicines sold to specified health care facilities and entities, known as 340B entities. Section 340B implements the ceiling prices by requiring the Secretary of Health and Human Services to enter into contracts setting forth the Act's pricing restrictions, and drug manufacturers are required to enter into those contracts as a condition of participation in Medicaid. 42 U.S.C. §§ 1396b(i)(10), 1396r-8(a)(1), (5).

In the decision below, the Ninth Circuit held that covered 340B entities have a private right of action under "federal common law" to enforce the Act's pricing requirements, even though the Act itself contains no express or implied private right of action. The Ninth Circuit held that a plaintiff may pursue a federal common law claim as a third-party beneficiary of a contract that embodies statutory requirements.

The question presented is whether, in the absence of a private right of action to enforce a statute, federal courts have the federal common law authority to confer a private right of action on non-parties to the contract simply because the statutory requirement sought to be enforced is embodied in the contract.

## PARTIES TO THE PROCEEDING

Petitioners Astra USA, Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corp., Bristol-Myers Squibb Co., Pfizer Inc., Merck & Co., Inc. (f/d/b/a Schering-Plough Corp.), SmithKline Beecham Corp. (d/b/a GlaxoSmithKline), TAP Pharmaceutical Products Inc. (n/k/a Takeda Pharmaceuticals North America, Inc.), Wyeth, Inc., Wyeth Pharmaceuticals, Inc., Zeneca Inc., and ZLB Behring LLC were defendants in the district court and appellees in the court of appeals.

Respondent County of Santa Clara was the plaintiff in the district court and appellant in the court of appeals.

## RULE 29.6 STATEMENT OF CORPORATE DISCLOSURE

The corporate disclosure statement included in the petition for a writ of certiorari remains accurate.

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Ctrs. for Medicare & Medicaid Servs. ("CMS"), *Medicaid Drug Rebate Program Overview* (last modified Sept. 27, 2010), http://www.cms.gov/MedicaidDrugRebateProgram/ ..... 5

CMS, Drug Product Data (last modified Aug. 3, 2010), http://www.cms.gov/MedicaidDrugRebateProgram/09_DrugProdData.asp. ..... 5

CMS, Medicaid Drug Rebate Program Release No. 28 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp ..... 35

CMS, Medicaid Drug Rebate Program Release No. 29 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp ..... 35

CMS, Medicaid Drug Rebate Program Release No. 30 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp ..... 35-36

Gov't Accountability Office, GAO-05-102, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States* (2005) ..... 34, 35

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Health Res. & Servs. Admin., 2010 *Quarter 3 Statistics for 340B Covered Entities* (2010), *available at* ftp://ftp.hrsa.gov/bphc/pdf/opa/stats_2010_QTR_3.pdf ..... 7

Jean Hearne, Cong. Research Serv., *CRS Report for Congress: Prescription Drug Coverage Under Medicaid* (2008), *available at* http://aging.senate.gov/crs/medicaid16.pdf ..... 5

Joint Explanatory Statement on H.R. 5193, 138 Cong. Rec. S17890 (1992), *reprinted in* 1992 U.S.C.C.A.N. 4186 ..... 7-8

Krista Pedley & Tom Morris, Health Res. & Servs. Admin., *340B Drug Pricing Program: New Covered Entity Webinar 5* (2010), *available at* www.hrsa.gov/opa/340bnewlyeligible.ppt ..... 7

Restatement (Second) of Contracts § 304 cmt. b (1981) ..... 29

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IN THE

# Supreme Court of the United States

No. 09-1273

ASTRA USA, INC., *et al.*,
*Petitioners*,

v.

COUNTY OF SANTA CLARA,
ON BEHALF OF ITSELF AND ALL
OTHERS SIMILARLY SITUATED,
*Respondent*.

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## BRIEF FOR THE PETITIONERS

## OPINIONS BELOW

The decision of the court of appeals is reported at 588 F.3d 1237. Pet. App. 1a-29a. The previous opinion of the court of appeals is reported at 540 F.3d 1094. Pet. App. 30a-58a. The unreported district court decisions reviewed by the court of appeals are set forth at Pet. App. 79a-96a and 97a-124a.

## JURISDICTION

The court of appeals entered its decision on December 9, 2009. Pet. App. 1a. A petition for rehearing was denied on February 11, 2010. Pet. App. 125a. The petition for a writ of certiorari was

filed on April 21, 2010, and granted on September 28, 2010. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## STATUTORY PROVISIONS INVOLVED

The relevant provisions of Section 340B of the Public Health Service Act, 42 U.S.C. § 256b, and Section 1927 of Title XIX of the Social Security Act, 42 U.S.C. § 1396r-8, are set forth at Pet. App. 127a-164a.

## STATEMENT

This case presents the question whether a private plaintiff may sue as a third-party beneficiary of a government contract that incorporates the requirements of a federal statute that does not confer a private right to sue. The issue here arises under two inextricably interrelated and complex federal statutes—the Medicaid Rebate Act ("Medicaid Act") and Section 340B of the Public Health Service Act ("340B Act")—that impose drug-pricing obligations on drug manufacturers whose outpatient drugs are covered by Medicaid. Those statutory drug-pricing requirements can be enforced by the Secretary of Health and Human Services ("the Secretary"), but there is no provision—express or implied—for enforcement by private parties.

The Medicaid Act requires all drug manufacturers whose outpatient drugs are covered by Medicaid to enter into contracts with the Secretary. Those agreements are known as Medicaid Rebate Agreements, and under them the manufacturers agree to provide drug rebates to States. The Medicaid Act also requires the same drug manufacturers to enter into a separate contract with the Secretary, known as the Pharmaceutical Pricing Agreement ("PPA"),

pursuant to the 340B Act, 42 U.S.C. § 256b. *See* 42 U.S.C. § 1396r-8(a)(1), (5). Under the PPA, manufacturers agree to provide deeply discounted prices to certain health care providers and entities, *id.* § 256b(a), referred to as "340B entities."

The Medicaid Act specifies the formula for calculating rebates owed to States under the Medicaid program, and the 340B Act specifies the formula for calculating the ceiling prices that apply to purchases by 340B entities. Both the Medicaid rebate amounts and the Section 340B ceiling prices for a particular drug are based on the drug manufacturers' Average Manufacturer Price ("AMP") and Best Price ("BP") as prescribed and defined by the Medicaid Act. *Id.* §§ 256b(a), 1396r-8(c).

Congress specified that the manufacturers' obligations to calculate and report AMP and BP "shall" be incorporated into both the Medicaid Rebate Agreements and the PPA. *Id.* §§ 256b(a)(1), 1396r-8(b)(3)(A). The Medicaid Act thus mandates that Medicaid Rebate Agreements require drug manufacturers to calculate and report AMPs and BPs to the Secretary for Medicaid covered drugs. *Id.* § 1396r-8(b)(3)(A). The 340B Act similarly specifies that the PPA must require drug manufacturers to use their AMP and BP as defined in, and as regulated by the Secretary under, the Medicaid Act to calculate the ceiling price for Section 340B drugs. *Id.* § 256b(a)(1), (2).

In the decision below, the Ninth Circuit held that federal common law confers on 340B entities the right to sue to enforce the statutory requirement that drug manufacturers accurately calculate and report to the Secretary the AMP and BP for all Medicaid covered drugs and ceiling prices for all Section 340B

drugs, *even though the 340B Act itself concededly confers no private right of action to sue*. The court of appeals reasoned that, although there is no express or implied right of action to enforce the statutory drug price calculation and reporting requirements under the statute, 340B entities have a federal common law claim for breach of contract as third-party beneficiaries of the PPA between drug manufacturers and the Secretary under the 340B Act.

The Ninth Circuit thereby created under the federal common law the right to enforce the 340B Act's drug-pricing provisions where the statute itself confers no such right. Pet. App. 3a, 8a, 29a. This Court's jurisprudence forecloses the Ninth Circuit's creation of a private right of action. A suit to enforce the contract term incorporating the statutory pricing obligation asserts the same substantive right—the right to the 340B ceiling price for Medicaid covered drugs—as a suit to enforce the statute itself. Recognition of a cause of action under the common law thus would contravene congressional intent and create an end-run around this Court's private right of action jurisprudence. Such a cause of action would also seriously disrupt the statutory schemes of both the Medicaid Act and the 340B Act.

## I. Statutory Framework

### a. *The Medicaid Drug Rebate Program*

Since 1990, the Medicaid Act has "imposed a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements . . . with the Secretary . . . to provide rebates on their Medicaid sales of outpatient prescription drugs." *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 652 (2003). Thus, as Spending

Clause legislation, U.S. Const. Art. I, § 8, cl. 1, the Medicaid Act prohibits federal financial participation under Medicaid "with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1396r-8" through which manufacturers pay rebates to States. 42 U.S.C. § 1396b(i)(10); *accord id.* § 1396r-8(a)(1), (5); J.A. 69-86 (form Medicaid Rebate Agreement).[1]

Approximately 550 manufacturers have entered into rebate agreements with the Secretary covering more than 35,000 drugs. *See* Ctrs. for Medicare & Medicaid Servs. ("CMS"), *Medicaid Drug Rebate Program Overview* (last modified Sept. 27, 2010), http://www.cms.gov/MedicaidDrugRebateProgram/; CMS, *Drug Product Data* (last modified Aug. 3, 2010), http://www.cms.gov/MedicaidDrugRebateProgram/09_DrugProdData.asp. Manufacturers in 2005 paid approximately $11.1 billion in rebates to States. Jean Hearne, Cong. Research Serv., *CRS Report for Congress: Prescription Drug Coverage Under Medicaid* 13 (2008), *available at* http://aging.senate.gov/crs/medicaid16.pdf.

The Medicaid Act sets forth a drug-pricing formula that determines the amount of rebates manufacturers owe to States for covered outpatient drugs. The Act's drug-pricing provisions provided, for the time period relevant to this case, that if the drug is either

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[1] The statutory provisions cited herein and in the Pet. App. are to the statutes in effect during the time period at issue in this case (2001-2008). *See* Pet. App. 74a. Congress recently amended portions of the Medicaid Act and 340B Act. Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, 124 Stat. 119 (2010). Unless expressly noted, these amendments did not materially change the statutory provisions cited herein.

a "single source drug" or an "innovator multiple source drug," the rebate due on each unit paid under a state Medicaid plan is typically either (i) the difference between the AMP and the manufacturer's BP, or (ii) 15.1 percent of the AMP, whichever is greater. 42 U.S.C. § 1396r-8(c)(1)(A), (B), (C) & (c)(2). For other drugs, the rebate is 11 percent of the AMP. *Id.* § 1396r-8(c)(3). In certain circumstances, the Act also requires inflation adjustments that can affect the rebate amount. *Id.* § 1396r-8(c)(2). The Medicaid Act requires manufacturers to report regularly to the Secretary the AMP and BP for each of their covered outpatient drugs. *Id.* § 1396r-8(b)(3)(A).[2]

The Medicaid Act contains several provisions authorizing the Secretary to enforce these drug-pricing requirements. The Act permits the Secretary to "survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices" reported. *Id.* § 1396r-8(b)(3)(B).

The Act also authorizes suspension of the Medicaid Rebate Agreement and a $10,000 penalty per day if a manufacturer fails to report AMP and BP on a timely basis. *Id.* § 1396r-8(b)(3)(C)(i). A manufacturer that knowingly provides false AMP or BP information is potentially subject to civil monetary penalties of up to $100,000 per item. *Id.* § 1396r-8(b)(3)(C)(ii). The Secretary may terminate the Medicaid Rebate

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[2] For the period at issue in this case, AMP equaled the average price paid for the drug by entities in the "retail pharmacy class of trade," and BP equaled the lowest price available to any purchaser within the United States, with certain statutorily-specified exclusions. 42 U.S.C. § 1396r-8(k)(1), (c)(1)(C); *cf.* PPACA § 2503 (amending the definition of AMP and the formula for calculating the Medicaid rebate amount).

Agreement upon a manufacturer's violation of the Agreement or for "other good cause shown." *Id.* § 1396r-8(b)(4)(B)(i).

b. *The Section 340B Drug Ceiling Price Program*

Section 340B of the Public Health Service Act of 1992, 42 U.S.C. § 256b, requires drug manufacturers participating in the Medicaid program to offer discounted drug prices to 340B entities consisting of certain hospitals and clinics, also known as "safety net providers," that receive federal funds. *See id.* § 256b(a)(4) (listing covered entities). In 2009 alone, 340B entities purchased an estimated $6 billion in drugs under the Section 340B program. Krista Pedley & Tom Morris, Health Res. & Servs. Admin., *340B Drug Pricing Program: New Covered Entity Webinar* 5 (2010), *available at* www.hrsa.gov/opa/340bnewlyeligible.ppt. Today, more than 14,500 entities participate in the 340B program. *See* Health Res. & Servs. Admin., *2010 Quarter 3 Statistics for 340B Covered Entities* (2010), *available at* ftp://ftp.hrsa.gov/bphc/pdf/opa/stats_2010_QTR_3.pdf.

The 340B program is also Spending Clause legislation and is inextricably intertwined with the much larger Medicaid drug rebate program. The Medicaid Act dictates that, in order for outpatient prescription drugs to be covered by Medicaid, drug manufacturers must sign an agreement consenting to charge no more than the ceiling price required under the 340B Act. 42 U.S.C. § 1396r-8(a)(1), (5); *see* Joint Explanatory Statement on H.R. 5193, 138 Cong. Rec. S17890 (1992), *reprinted in* 1992 U.S.C.C.A.N. 4186, 4211 (stating that "use of [Medicaid] federal matching funds for payment for a covered outpatient drug [under State Medicaid plans] would be contingent on . . . a manufacturer's entering into . . . an agreement

with the Secretary of Health and Human Services (HHS) under which the manufacturer agrees to provide rebates or discounts to" 340B entities).

The 340B Act incorporates by reference the AMP and BP definitions and pricing methodology from the Medicaid Act and provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which" the manufacturer may not charge more than a statutorily defined price, referred to generally as the "ceiling price." 42. U.S.C. § 256b(a)(1). The ceiling price is "the average manufacturer price for the drug under [the Medicaid Act] in the preceding calendar quarter, reduced by [a] rebate percentage." *Id.*

Thus, the 340B ceiling price equals the AMP defined in the Medicaid Act, *see supra* p. 6 n.2, reduced by the "rebate percentage," which is defined in the 340B Act as the "average total rebate required under" the Medicaid rebate program "with respect to the drug . . . during the preceding calendar quarter; divided by . . . the average manufacturer price for such a unit of the drug during such quarter." 42 U.S.C. § 256b(a)(2)(A). The rebate percentage in turn is based on a statutory formula in the Medicaid Act that requires calculation of, *inter alia*, a manufacturer's BP. *Id.* (citing 42 U.S.C. § 1396r-8(c)). Because of the ceiling price requirements, 340B entities receive large discounts on covered outpatient drugs.

As required by the 340B Act, the statutory ceiling price requirements are set forth in the PPA, which is a form document prepared by the Health Resources and Services Administration ("HRSA") of the Department of Health and Human Services ("HHS"). Pet. App. 165a-181a (form PPA). The PPA recites the

340B Act's obligation that manufacturers charge 340B entities no more than the statutory ceiling price. *Id.* at 170a (PPA ¶ II(a)). The PPA expressly incorporates by reference the manufacturer's statutory drug-pricing obligations to report AMP and BP in accordance with the Medicaid Act's drug rebate provisions. *Id.* at 170a-71a (PPA ¶ II(a)-(d)). The PPA also provides that the Secretary is entitled to "reasonable access to records of the Manufacturer relevant to the Manufacturer's compliance with the terms of the Agreement." *Id.* at 171a (PPA ¶ II(e)).

If the Secretary believes that a manufacturer "has not complied" with Section 340B's requirements, "or has refused to submit reports, or has submitted false information," the PPA authorizes the Secretary to "initiate [an] informal dispute resolution process." *Id.* at 174a (PPA ¶ IV(c)). As part of this process, "the Secretary may require the Manufacturer to reimburse the entity for discounts withheld and can also terminate" the PPA. *Id.* Termination of the PPA means that the manufacturer no longer meets the requirements for Medicaid coverage for the manufacturer's outpatient drugs. *Id.* The PPA further provides that the agreement "shall be construed in accordance with Federal common law." *Id.* at 180a (PPA ¶ VII(g)). The PPA contains no provisions that allow a 340B entity (or any other third party) to enforce its terms.

## II. Proceedings Below

a. The County of Santa Clara, California, on behalf of 340B entities in California and California counties that fund 340B entities, brought this putative class action against the petitioners, which are all pharmaceutical manufacturers. The County initially filed suit in state court, alleging that petitioners violated

state law by charging more than the ceiling prices required by the 340B Act. The suit, however, did not identify any particular overcharge by any manufacturer with respect to any drug sold to any covered entity.

Petitioners removed the suit to the U.S. District Court for the Northern District of California, which dismissed the state law claims. The County amended the complaint to add a third-party beneficiary breach of contract claim alleging that county entities "were overcharged for prescription and over-the-counter drugs and pharmaceutical products ('drugs') under the §340B Program pursuant to the [340B] Act." J.A. 30 (2d Am. Compl. ¶ 1). Claiming to be "the intended beneficiaries of the PPA," the County alleged that the class members were "entitled to damages they sustained as a result of [petitioners'] breach of contract." *Id.* at 64 ¶ 104.

The district court again dismissed all the state law claims, noting that "plaintiff's statement of facts is based largely on government reports that never identified the manufacturer, drug or 340B entity." Pet. App. 112a. The court also dismissed the third-party beneficiary breach of contract claim under the PPA, holding that neither the statute nor the PPA reflects an intent to bestow on private parties the right to sue to enforce the 340B Act's pricing requirements. *Id.* at 119a. The County appealed the dismissal of only the third-party beneficiary breach of contract claim under the PPA.

b. The Ninth Circuit reversed and held that federal common law provides a third-party beneficiary breach of contract action for 340B entities to enforce the Act's drug-pricing provisions as incorporated into the PPA. Pet. App. 30a-58a. The court of

appeals held that 340B entities "are intended direct beneficiaries of the PPA and have the right as third parties to bring claims for breach of that contract." *Id.* at 36a.

The court further held "that allowing such suits under the PPA is consistent with Congress' intent in enacting the Section 340B program, *even though the statute itself does not create a federal private cause of action.*" *Id.* (emphasis added). The Ninth Circuit found that the claim "presents no far-reaching question that requires expertise or uniformity in administration" of the drug ceiling price program because 340B entities could challenge ceiling prices based only on "the average manufacturer price *reported* to the Secretary" and could not "claim that the reported figure was itself somehow erroneous." *Id.* at 57a (internal quotation marks omitted).

On remand, the district court interpreted the Ninth Circuit's statement that the suit involved only the prices "*reported* to the Secretary" to bar litigation of the drug manufacturers' underlying pricing data and the methods by which they derived the AMP and BP figures reported to the Secretary. *Id.* at 80a-81a.

c. On interlocutory appeal, the Ninth Circuit invited the Secretary to file an amicus brief. *Id.* at 2a n.**. In response to the Ninth Circuit's invitation, the United States, setting forth the considered judgment of the Secretary, expressed the view that it "never imagined that a 340B entity could bring a third-party beneficiary lawsuit" and that such a suit would confer "rights never intended by the PPA's signatories." *See* Brief of the United States of America as Amicus Curiae in Support of the Judgment Below at 13, 21, *County of Santa Clara v. Astra USA, Inc.*, No. 09-15216 (9th Cir. Oct. 27, 2009) ("Gov't

Br."), 2009 WL 4089524. The United States also concluded that discovery in the suit was barred by the Medicaid Act's requirement that the Secretary ensure the confidentiality of drug manufacturers' pricing and drug sales information underlying the calculation of AMPs and BPs. *Id.* at 19-21; *see* 42 U.S.C. § 1396r-8(b)(3)(D).

The United States further explained that the Medicaid drug rebate program confers considerable discretion on drug manufacturers to make reasonable assumptions in calculating AMPs and BPs under the Medicaid Act, which in turn are used to calculate ceiling prices under the 340B Act. Gov't Br. at 4-5. As a result, the United States explained that the recognition of a private right of action to enforce the Medicaid Act's or the 340B Act's pricing requirements would interfere with the Secretary's exclusive responsibility to administer both programs on a nationwide, uniform basis. The United States thus explained that "allowing suits like this would threaten the orderly operation of *both* programs." *Id.* at 19 (emphasis in original).

The United States also reasoned that the manner in which the Medicaid rebates and 340B discounts are calculated create conflicting incentives for recipients of the respective programs. The United States observed that, although relatively high AMPs generally increase the price that manufacturers may charge 340B entities (to the *detriment* of those 340B entities), high AMPs simultaneously increase the manufacturers' much larger rebate obligations to the States (which *benefits* the Medicaid program). *Id.* at 31.

Those conflicting incentives, the United States explained, highlight the need to leave the adminis-

tration and enforcement of the 340B Act and Medicaid Act where Congress placed it, *i.e.*, with the Secretary, who has the expertise to resolve complex issues of pricing methodology and difficult issues of statutory interpretation under both programs. *Id.* at 32.

Soon after the United States filed its amicus brief, the Ninth Circuit issued a superseding decision that reissued the panel's earlier decision but struck the language that had suggested the suit was limited only to the drug-pricing information reported to the government. *Compare* Pet. App. 56a-58a, *with id.* at 28a-29a. Although the court of appeals had invited the Secretary's participation, the superseding decision neither discussed nor deferred to the Secretary's conclusion that permitting the litigation to proceed would be disruptive to both statutory schemes.

## SUMMARY OF ARGUMENT

By allowing a private plaintiff to bring a federal common law claim based on a statute that does not provide for any private right of action, the Ninth Circuit's decision contravenes congressional intent and decades of this Court's private right of action jurisprudence. Accordingly, it should be reversed.

A. The 340B Act maximizes health coverage by allowing safety net providers to buy drugs at a discounted price. But Congress chose not to provide an express or implied private cause of action to allow 340B entities to enforce the statute's discount pricing provisions through damages suits.

The law is clear: unless Congress intends to create a cause of action, "a cause of action does not exist and courts may not create one." *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001). This black-letter rule

reflects a concern, grounded in separation of powers principles, that the judiciary should not embrace a dispute that Congress has not empowered the courts to resolve. *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008). That rule controls this case.

B. The County has conceded at every stage of this litigation—in the district court, in the court of appeals, and in this Court—that the 340B Act confers no private right of action or remedy in favor of 340B entities. C.A. Supp. ER at 66 (9th Cir. Jan. 17, 2007); Pet. App. 22a; Br. in Opp. 4. Nonetheless, the County maintains that this suit seeks not to enforce the 340B Act, but rather to enforce the PPA *contract* between the drug manufacturers and the Secretary. Yet enforcing the contract and enforcing the 340B statute are one and the same.

The County is not a party to the PPA and did not negotiate the contract's terms. Rather, the Secretary promulgated the PPA's language, following the express mandate of Congress. And neither the statute nor the PPA provides third parties with any right to enforce its terms.

In the 340B Act, Congress mandated the drug ceiling price provisions to be incorporated into the terms of the contract. And the PPA correspondingly incorporates by reference the 340B Act's ceiling price provisions. Thus, the County's own complaint makes clear that the 340B Act is the sole source of the precise contractual terms allegedly breached. *See, e.g.*, J.A. 41-42, 44 (2d Am. Compl. ¶¶ 32, 39, 40).

C. The Ninth Circuit held that federal common law creates a cause of action for non-parties to enforce the PPA, despite that neither the contract nor the statute, by its terms, allows such lawsuits. If

Congress did not choose to create a private right of action to enforce these statutory terms, then federal common law on its own cannot create such a right.

This Court in *Sandoval* held that an agency cannot by regulation create a cause of action to enforce a statute. 532 U.S. at 291. The agency has no more authority to create private rights to enforce a statute when the agency implements congressional policy via a contract. The PPA thus could not have created a private right of action in favor of 340B entities even if the PPA had attempted to do so explicitly.

A plaintiff may not circumvent congressional intent "by artful pleading" or "the simple expedient of putting a different label" on its cause of action to obtain a remedy not provided by Congress. *Brown v. Gen. Servs. Admin.*, 425 U.S. 820, 833 (1976). When a party seeks to enforce a contractual provision that is *in haec verba* with a statutory provision that Congress mandated to be incorporated into a government contract, that action is indistinguishable from an action to enforce the statute itself.

When this Court has faced analogous attempts by parties to circumvent congressional intent by asserting contract-based claims to enforce other federal statutes, it has held that Congress's intent controls. *See United States v. Erika, Inc.*, 456 U.S. 201, 206-08 (1982); *Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754, 784 (1981). Congressional intent here similarly requires dismissal of the suit.

D. Private enforcement of the 340B Act would seriously interfere with administration of the 340B drug ceiling price program, as well as the vastly larger Medicaid drug rebate program whose pricing methodology is expressly incorporated into the 340B

Act. Oversight over how manufacturers calculate and report BP and AMP—calculations that are exceedingly complex and technical—should not be left to private plaintiffs whose incentives inevitably will diverge from those of the Secretary.

Congress has delegated enforcement of the 340B Act not to 340B entities, but to the Secretary, who has the expertise and perspective to resolve the multitude of difficult issues that determine the calculation of AMP, BP, and the resulting 340B ceiling prices. Congress also provided the Secretary authority to impose substantial penalties and other enforcement mechanisms to ensure that drug manufacturers comply with the 340B Act. Allowing private lawsuits to interfere with the Secretary's judgment would, in the United States's assessment, "conflict with Congress's comprehensive administrative and enforcement scheme" and the agency's ability to administer *both* the 340B Act and the Medicaid Act on a uniform, nationwide basis. Gov't Br. at 13.

E. The federal common law of contracts does not create a cause of action where Congress has failed to do so. A federal court's exercise of federal common law is limited by "the paramount authority of Congress." *Nw. Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95 (1981) (internal quotation marks omitted); *City of Milwaukee v. Illinois*, 451 U.S. 304, 313-14 (1981).

Even when federal courts have "express congressional authorization to devise a body of law directly," *Sosa v. Alvarez-Machain*, 542 U.S. 692, 726 (2004), a private party must still demonstrate that Congress intended a private right of action to enforce the statute. Similarly, where Congress has "occupied the field through the establishment of a comprehensive

regulatory program supervised by an expert administrative agency," private remedies are limited to those enacted by Congress. *City of Milwaukee*, 451 U.S. at 317.

All roads in this case lead to the same place: Congress declined to confer a private right of action on 340B entities to enforce the drug price ceiling provisions of the 340B Act. Covered entities therefore cannot invoke the federal common law to sue for damages from an alleged breach of the PPA when the right sought to be enforced is derived from an Act of Congress.

## ARGUMENT

This common law breach of contract suit by purported third-party beneficiaries to the PPA should have ended upon the uncontested proposition that Congress did not confer on 340B entities an express or implied private right of action to enforce the 340B Act's drug-pricing obligations. A purported beneficiary of a federal statute is not entitled to enforce a statutory obligation simply because Congress mandated that the obligation be incorporated into a government contract. A private right of action to enforce a federal statute must be created by Congress. *E.g.*, *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008); *Gonzaga Univ. v. Doe*, 536 U.S. 273, 283-84 (2002); *Alexander v. Sandoval*, 532 U.S. 275, 286 (2001); *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 173 (1994); *Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754, 771-73 (1981); *Touche Ross & Co. v. Redington*, 442 U.S. 560, 568 (1979).

That principle disposes of this case. Congress is the source of the drug-pricing obligations in the contract that the 340B entities seek to enforce. Congress must be the source of a judicial remedy to redress any alleged violation of those obligations. The absence of a private right of action under the statute accordingly forecloses a common law suit by purported third-party beneficiaries to the PPA.

## A COMMON LAW THIRD-PARTY BENEFICIARY CLAIM FOR BREACH OF CONTRACT CONFLICTS WITH THE ABSENCE OF A PRIVATE RIGHT OF ACTION UNDER THE STATUTE

### A. Only Congress Can Create A Right To Sue To Enforce An Act Of Congress

1. Absent congressional intent to create a private right and remedy, "a cause of action does not exist and courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute." *Sandoval*, 532 U.S. at 286-87. In other words, "[t]he federal judiciary will not engraft a remedy on a statute, no matter how salutary, that Congress did not intend to provide." *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 145 (1985) (quoting *California v. Sierra Club*, 451 U.S. 287, 297 (1981)).

This bedrock principle "reflects a concern, grounded in separation of powers, that Congress rather than the courts controls the availability of remedies for violations of statutes." *Stoneridge*, 552 U.S. at 165 (quoting *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 509 n.9 (1990)). Without congressional intent, the judiciary's recognition of a private right to enforce a statute "necessarily extends its authority to embrace

a dispute Congress has not assigned it to resolve." *Id.* at 164 (internal quotation marks omitted).

"Though the rule once may have been otherwise, *see J. I. Case Co.* v. *Borak*, 377 U.S. 426, 432-433 (1964), it is settled that there is an implied cause of action only if the underlying statute can be interpreted to disclose the intent to create one." *Stoneridge*, 552 U.S. at 164. The Court thus has "retreated" from its "previous willingness to imply a cause of action where Congress has not provided one." *Corr. Servs. Corp. v. Malesko*, 534 U.S. 61, 67 n.3 (2001); *see also id.* at 75 (Scalia, J., concurring) (The *Borak* approach is "a relic of the heady days in which this Court assumed common-law powers to create causes of action—decreeing them to be 'implied' by the mere existence of a statutory or constitutional prohibition."). The once permissive approach to inferring a private right of action has long since been "abandoned." *Sandoval*, 532 U.S. at 287.

Under modern precedent, "recognition of any private right of action for violating a federal statute must ultimately rest on congressional intent to provide a private remedy." *Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1102 (1991); *accord Sierra Club*, 451 U.S. at 297 ("[T]he focus of the inquiry is on whether Congress intended to create a remedy." (citing *Univs. Research Ass'n, Inc.*, 450 U.S. at 771-72)). "Like substantive federal law itself, private rights of action to enforce federal law must be created by Congress." *Sandoval*, 532 U.S. at 286. The judicial "task is limited solely to determining whether Congress intended to create the private right of action asserted." *Touche Ross & Co.*, 442 U.S. at 568. The statute must reveal "an intent to create not just

a private right but also a private remedy." *Sandoval*, 532 U.S. at 286.

2. Judicial power to infer a private right of action is especially limited where, as here, a private party seeks to enforce provisions of Spending Clause legislation. *See, e.g.*, *Gonzaga Univ.*, 536 U.S. at 283; *Sandoval*, 532 U.S. at 286; *Pennhurst State Sch. & Hosp. v. Halderman*, 451 U.S. 1 (1981). "[I]f Congress intends to impose a condition on the grant of federal moneys, it must do so *unambiguously*." *Pennhurst*, 451 U.S. at 17 (emphasis added); *see, e.g.*, *Barnes v. Gorman*, 536 U.S. 181, 186 (2002); *Davis v. Monroe Cnty. Bd. of Educ.*, 526 U.S. 629, 640 (1999). In the few cases where the Court has found Spending Clause legislation to give rise to enforceable rights, such as in Title VI of the Civil Rights Act of 1964 and Title IX of the Education Amendments of 1972, "Congress spoke in terms that could not be clearer." *Gonzaga Univ.*, 536 U.S. at 280 (internal quotation marks omitted).

The Section 340B ceiling price and Medicaid drug rebate programs are Spending Clause enactments. *See supra* pp. 4-5, 7-8. The "typical" remedy for noncompliance with Spending Clause legislation is for the federal government to terminate provision of funds. *Gonzaga Univ.*, 536 U.S. at 280 (quoting *Pennhurst*, 451 U.S. at 28). The PPA follows precisely this approach—it authorizes the Secretary to terminate the agreement if a manufacturer fails to comply with its obligations, thus barring the manufacturer from receiving coverage for its outpatient drugs under Medicaid. *See* Pet. App. 174a (PPA ¶ IV(c)).

Thus, any right of action by claimed beneficiaries of those programs must be based on "clear and unambi-

guous" congressional intent to create both a private right and a private remedy. *Gonzaga Univ.*, 536 U.S. at 284, 290. As demonstrated below, the requisite clarity necessary to find a private cause of action in this case is manifestly absent.

### B. This Suit Seeks Private Enforcement Of A Statute

1. The County has dressed up an implied right of action claim in breach-of-contract clothes. The litigation began when the County filed this putative class action alleging that 340B entities "were overcharged for prescription and over-the-counter drugs and pharmaceutical products ('drugs') under the §340B Program *pursuant to the [340B] Act*." J.A. 30 (2d Am. Compl. ¶ 1) (emphasis added).[3] The complaint alleged, based on information and belief, *id.* at 32 ¶ 7, that those entities were charged more than the "*statutorily defined* discount on outpatient drugs." *Id.* at 30 ¶ 2 (emphasis added).

This suit thus unquestionably seeks to enforce the pricing obligations of the 340B Act. Indeed, the complaint repeatedly acknowledges that the 340B Act is the source of the contractual term allegedly breached. *See e.g.*, *id.* at 41-42 ¶ 32 ("§340B requires pharmaceutical manufacturers to ensure that §340B Participants pay no more than the 'ceiling price,' a discounted price compared to the average manufacturers' price for any pharmaceutical product."); *id.*

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[3] Respondent filed a third amended complaint while its request for interlocutory review was pending. The third amended complaint added new plaintiffs and retained the third-party beneficiary breach of contract claim based on the statutory ceiling price obligations that are incorporated into the PPA. Third Am. Compl. ¶¶ 72-79 (filed Dec. 23, 2008).

at 44 ¶ 39 ("Section 340B . . . requires [drug manufacturers] to agree to be bound by the PPA in order to participate in the §340B Program."); *id.* ¶ 40 ("Under both §340B and the PPA, [drug manufacturers] are required to ensure that the §340B Participants . . . pay no more for any product that the §340B ceiling price.").

2. Notwithstanding that the gravamen of this suit is that petitioners allegedly violated the ceiling price requirements of the 340B Act, the County did not bring its claim directly under the 340B statute. To the contrary, in the trial court, the County acknowledged that "there is no federal private right of action under the 340B Program." C.A. Supp. ER 66; *see also* Pet. App. 22a (noting "Santa Clara's concession before the district court that there is no private federal cause of action under § 256b.").

In the Ninth Circuit, the County likewise observed that "the statute here neither creates nor precludes any remedy, it simply provides for a contract." Appellants' Reply Brief at 10, *County of Santa Clara v. Astra USA, Inc.*, No. 06-16471 (9th Cir. Feb. 20, 2007), 2007 WL 894881; *accord* Pet. App. 22a n.15. And in this Court, the County represented that "the County's position is not that the statute creates an implied right of action to sue for violation of the statute." Br. in Opp. 4 (internal brackets and quotation marks omitted); *id.* ("[T]he County seeks to vindicate the rights of its covered entities under contracts . . . that were created by a federal statute which expressly provides them no remedy . . . .").

Instead of formally bringing a claim under the 340B Act, the County asserted a "federal common law" third-party beneficiary claim for breach of contract. Appellants' Opening Brief at 3, *County of*

*Santa Clara v. Astra USA, Inc.*, No. 06-16471 (9th Cir. Nov. 22, 2006), 2006 WL 4040345; J.A. 63-64 (2d Am. Compl. ¶¶ 101-04). That claim alleges that 340B entities are third-party beneficiaries to the PPA on the theory that the contracting parties intended that 340B entities "pay no more than the 340B ceiling price for covered drugs." J.A. 64 (2d Am. Compl. ¶ 102). Quoting paragraphs II and II(a) of the PPA, the complaint alleges that the PPA confers a right of judicial enforcement on behalf of covered entities: "Pursuant to requirements under section 340B . . . the Manufacturer agrees . . . to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported . . . ." *Id.*

The contract claim further contends that the manufacturers "breached, and continue to breach, their contractual obligations under the PPA by charging plaintiffs and the Class members more than the §340B ceiling price for covered drugs." *Id.* ¶ 103. The County thus seeks to prove that 340B entities were charged more than the 340B Act ceiling price by showing that manufacturers miscalculated and misreported to the Secretary the AMP and BP components of the 340B ceiling price. As the County described its claim, "[s]ince the ceiling price is dependent on the AMP and best price, logically and legally, plaintiffs would need to discover the data that comprised the prices charged." Pl.'s Pet. to Appeal at 5, *County of Santa Clara v. Astra USA, Inc.*, No. 08-80200 (9th Cir. Dec. 11, 2008); *cf.* 42 U.S.C. §§ 256b(a)(2)(A), 1396r-8(c)(1)(A) & (C) (setting forth BP as part of the formula for determining the 340B "rebate percentage").

The substantive right that the County seeks to enforce thus derives from an Act of Congress. The allegedly breached contractual term—the requirement not to charge 340B entities more than the 340B ceiling price—is *statutorily required*. The Medicaid Act, as a condition of statutory coverage for outpatient drugs, mandates that drug manufacturers enter into a PPA under which they agree not to charge 340B entities more than the Section 340B ceiling price. 42 U.S.C. § 1396r-8(a)(1), (5).

The 340B Act in turn explicitly requires the PPA to provide that the amount the manufacturer charges a covered entity for covered drugs cannot "*exceed an amount equal to the average manufacturer price for the drug under [the Medicaid Act] . . . reduced by the rebate percentage*." 42 U.S.C. § 256b(a)(1) (emphasis added); *compare* Pet. App. 170a (PPA ¶II(a)). The PPA also incorporates the statutory requirement that manufacturers determine the 340B ceiling price using the AMP and BP figures calculated under the Medicaid Act. Section II(a) provides that the manufacturers must use the AMP "reported . . . to the Secretary in accordance with the Manufacturer's responsibilities under [the Medicaid Act]." Pet. App. 170a (PPA ¶II(a)).

The PPA includes definitions of AMP and BP, which "have the meanings specified in the [340B] Act and [the Medicaid Act]." *Id.* at 165a (PPA ¶ I). Thus, at every point in the determination of the ceiling price, manufacturers are directed by the PPA to comply with the provisions of the 340B Act and the relevant drug rebate provisions of the Medicaid Act. As the Ninth Circuit below candidly acknowledged, the PPA is not the product of "a conventionally negotiated contract." *Id.* at 20a n.13. In the words of the

court of appeals: "Santa Clara seeks enforcement of an obligation created by a nationwide federal contract whose terms are *mandated by federal statute*." *Id.* at 9a n.5 (emphasis added).

### C. A Third-Party Beneficiary Suit For Breach Of Contract Would Circumvent The Absence Of A Private Right Of Action Under The 340B Act

1. When a third party seeks to enforce a contractual provision that is *in haec verba* with a statutory provision that Congress mandated be incorporated into a contract, recognition of a common law third-party beneficiary breach of contract action conflicts with the bedrock requirement that only Congress may authorize private enforcement of an Act of Congress. This case well illustrates the point. Although the Ninth Circuit expressly assumed that Congress did *not* intend the 340B Act's pricing obligations to be enforced by private parties, Pet. App. 8a, 22a n.15, 29a, the court of appeals invented such a right anyway under the federal common law of contract.

The Ninth Circuit's holding erroneously assumes the Secretary by contract may confer a private right of action by 340B entities that is not provided in the statute itself. This Court's decision in *Alexander v. Sandoval*, 532 U.S. 275 (2001), establishes that even an affirmative intent by the Executive Branch to create substantive rights in the PPA could not trump the absence of an implied right of action in the statute. The Court in *Sandoval* squarely rejected the principle that "language in a [government] regulation can conjure up a private cause of action that has not been authorized by Congress." 532 U.S. at 291. The Court explained that "[a]gencies may play the

sorcerer's apprentice but not the sorcerer himself." *Id.*

*Sandoval* forecloses any argument that the parties, by executing the PPA, could have somehow conferred a private right of action on 340B entities despite the lack of congressional intent to do so. The Secretary had no more authority to create a private cause of action to enforce the 340B Act when she entered into the PPA than had she by regulation purported to create a private right of action in favor of Section 340B entities. The PPA thus could not override the absence of an implied right of action even if the PPA explicitly had purported to create a private right of action in favor of 340B entities.

2. In analogous contexts, this Court has held that congressional intent is controlling over the contracting parties' intent. In *Universities Research Association, Inc. v. Coutu*, 450 U.S. 754 (1981), this Court looked to congressional intent, rather than the terms of a contract, to determine that a private party had no right to sue to enforce statutory rights incorporated in the contract. That decision held that a purported beneficiary of a government contract could not sue for private enforcement of minimum-wage requirements set forth in the Davis-Bacon Act, 40 U.S.C. § 276a(a), which the plaintiff-employee alleged were incorporated into the contract. 450 U.S. at 784. The plaintiff did not pursue a private right of action under the Davis-Bacon Act but asserted that the contractor breached the contract that had, by operation of law, incorporated the statutory wage obligations. *Id.* at 764-67; *Coutu v. Univs. Research Ass'n, Inc.*, 595 F.2d 396, 397-98 (7th Cir. 1979) (describing claims).

In holding that the plaintiff had no right to sue, the Court exclusively focused on whether Congress intended to create a private right of action. 450 U.S. at 770-71. This Court found the fact "that an enactment is designed to benefit a particular class does not end the inquiry; instead, it must also be asked whether the language of the statute indicates that Congress intended that it be enforced through private litigation." *Id.* at 771. *Universities Research Association* thus confirms that when a private party seeks to enforce statutory rights—either under the statute itself or under a government contract incorporating the statutory requirement—the dispositive question is whether Congress intended that the statutory obligation "be enforced through private litigation." *Id.*

This Court similarly has held that private parties may not circumvent congressional intent to withhold a private right of action by dressing up a claim to enforce statutory requirements in breach-of-contract garb. In *United States v. Erika, Inc.*, 456 U.S. 201, 206-08 (1982), the Court held that the structure of the Medicare Act reflected an implied legislative intent to preclude judicial review of determinations by private insurance carriers of the amount of benefits payable under Part B of the Medicare program, 42 U.S.C. § 1395j *et seq.* (1976). The Court rejected the plaintiff's claim that, separate from any rights arising under the Act, a Medicare provider derived a substantive right to seek review of the carrier's determination "from an implied-in-fact contract with the United States, or *as a third-party beneficiary to [the carrier's] contract with the United States.*" 456 U.S. at 211 n.14. (emphasis added).

Those "arguments fail because any such contracts with the United States necessarily would include the statutory preclusion of review of hearing officers' determinations regarding the amount of Part B benefits." *Id.* The Court reasoned that the judicial task was "at an end" because Congress did not intend to provide for judicial review of the carrier's determination. *Id.* at 211. The same principle precludes 340B entities from using a pleading device to evade the absence of an implied right of action to enforce the 340B Act.

A plaintiff may not circumvent congressional intent "by artful pleading" or "the simple expedient of putting a different label" on his cause of action to obtain a remedy not provided by Congress. *Brown v. Gen. Servs. Admin.*, 425 U.S. 820, 833 (1976); *see also Tenet v. Doe*, 544 U.S. 1, 8 (2005) (holding that preclusion of judicial review under *Totten v. United States*, 92 U.S. 105 (1876), applies "[n]o matter the clothing in which [plaintiffs] dress their claims"). Because the 340B Act does not confer on 340B entities a right of action, the PPA between the government and the manufacturers "necessarily . . . include[s] the statutory preclusion of review" of the drug manufacturers' drug-pricing determinations. *Erika, Inc.*, 456 U.S. at 211 n.14.

3. A third-party beneficiary claim for breach of contract renders the absence of a private right of action meaningless since the substantive right to enforce the drug-pricing requirements is the same under either doctrine. A private right of action by third parties to enforce the *contract's* ceiling price obligations is indistinguishable from a private right of action to enforce the *statutory* ceiling price obligations set forth in the contract.

When Congress requires a statutory obligation to be incorporated into a government contract, a private suit under a third-party beneficiary theory "is but another aspect of the implied right of action argument." *Hodges v. Atchison, Topeka & Santa Fe Ry. Co.*, 728 F.2d 414, 416 (10th Cir. 1984). Common law third-party beneficiary suits "are indirect attempts at privately enforcing the [statutory requirements] contained in the [Act]," and would interfere with congressional intent "to the same extent as would a cause of action directly under the statute." *Grochowski v. Phoenix Constr.*, 318 F.3d 80, 86 (2d Cir. 2003) (internal quotation marks omitted). Where "no private right of action exists under the relevant statute," a plaintiff's efforts to bring common law claims "are clearly an impermissible 'end run' around the [Act]." *Id.*; *cf. Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 683 (Thomas, J., concurring) (questioning whether a third-party beneficiary breach of contract claim would conflict with the Court's implied right of action and Spending Clause cases).

The Ninth Circuit's decision vividly illustrates the extent to which the creation of a third-party beneficiary right in these circumstances would circumvent the stringent requirements necessary for inferring a private right of action. The third-party beneficiary doctrine gives parties to a contract "the power, if they so intend, to create a right in a third person." Restatement (Second) of Contracts § 304 cmt. b (1981). The court of appeals thus held that "the parties to the PPA clearly intended to grant covered entities enforceable rights as intended beneficiaries of that agreement." Pet. App. 13a. But because Congress created the ceiling price obligations, only

Congress can create a private right to enforce those obligations.

As discussed, no amount of intent on the part of the parties, including the Executive Branch, to create a private right or remedy can trump the fact that Congress did not provide for such a remedy in the statute. *See supra* pp. 25-26. And here, the parties' intent and Congress's intent are one and the same. Indeed, the Ninth Circuit seemingly ignored the view of the United States that the Secretary "never imagined that a 340B entity could bring a third-party beneficiary lawsuit." Gov't Br. at 21. As the United States aptly stated, letting this suit proceed would "accord . . . rights never intended by the PPA's signatories." *Id.* at 13.

The court of appeals nonetheless reasoned that it was "unable to discern any substantial purpose of the PPA *other* than to grant eligible covered entities a discount on covered drugs." Pet. App. 15a. The court accordingly held that because the 340B program directly benefits covered entities in the form of drug discounts, 340B entities are intended third-party beneficiaries of the contract. As stated by the court of appeals: "the right to sue inheres in one's status as an intended beneficiary." *Id.* at 11a.

That analysis is categorically barred by this Court's settled private right of action and Spending Clause jurisprudence, which hold that a private remedy cannot be based on the status of the plaintiff as an intended beneficiary of a federal program. The relevant inquiry is whether "Congress intended to create a federal right." *Gonzaga Univ.*, 536 U.S. at 283 (emphases removed). "The question is not simply who would benefit from the Act, but whether Congress intended to confer federal rights upon those

beneficiaries." *Sierra Club*, 451 U.S. at 294; *accord, e.g., Sandoval*, 532 U.S. at 286-87; *Univs. Research Ass'n*, 450 U.S. at 771; *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 24 (1979). "[T]he question whether Congress intended to create a private right of action is definitively answered in the negative where a statute by its terms grants no private rights to any identifiable class." *Gonzaga Univ.*, 536 U.S. at 283-84 (brackets and quotation marks omitted).

That analysis should have been the beginning and end of this case. The County for good reason conceded that Congress did not confer on 340B entities enforceable rights and private remedies. The 340B Act provides that "[t]he Secretary shall enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . purchased by a covered entity . . . does not exceed [the ceiling price]." 42 U.S.C. § 256b(a)(1).

Statutory language "simply 'phrased as a directive to federal agencies engaged in the disbursement of public funds,'" "provides no support for the implication of a private remedy." *Univs. Research Ass'n*, 450 U.S. at 772-73 (quoting *Cannon v. Univ. of Chi.*, 441 U.S. 677, 693 n.14 (1979)); *see also Gonzaga Univ.*, 536 U.S. at 287; *Sandoval*, 532 U.S. at 288. And no provision of the 340B Act contains the clear and unambiguous language necessary to infer congressional intent to create a private right of action. *Sandoval*, 532 U.S. at 288.

The Ninth Circuit concluded that the third-party beneficiary claim was permissible because the 340B Act "does not abrogate" private contract suits by third parties. Pet. App. 24a n.16. The court of appeals

based this conclusion on the rule that the third-party beneficiary doctrine does not apply to the extent that application "would contravene the policy of the law authorizing the contract or prescribing remedies for its breach." Pet. App. 27a (quoting Restatement (Second) of Contracts § 313(1)). But that rule starts from the wrong premise—that third parties can derive rights from contracting parties unless a court ascertains a congressional intent to foreclose the right.

There is no free-standing cause of action under the federal common law in favor of 340B entities that Congress must affirmatively "abrogate." Rather, Congress must affirmatively authorize the cause of action. *See supra* pp. 18-21; *see also Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255 n.5. (1993) ("The dissent expresses its certitude that 'the statute clearly does not bar such a suit.' That, of course, is not the issue. The issue is whether the statute affirmatively *authorizes* such a suit." (citation omitted) (emphasis in original)). Congress did not do so here. The court of appeals accordingly erred in arrogating to itself the power to create an action on behalf of 340B entities absent congressional authorization.

### D. Private Suits Would Seriously Disrupt The Comprehensive Statutory Schemes Under The 340B Act And The Medicaid Act

1. As the Secretary explained, allowing a private right of action would also interfere with the Secretary's orderly regulation of both the 340B program and the much larger Medicaid program. *See* Gov't Br. at 19. Disregarding that view, however, the Ninth Circuit sought to buttress its recognition of a private right of action by opining that private

suits are "wholly compatible with the Section 340B program's objectives" to ensure "that drug companies comply with their obligations under the program and provide those discounts." Pet. App. 26a, 27a. The court similarly stated its view that it "'seemed more sensible' to permit third parties to sue as intended beneficiaries than to 'place the entire burden of enforcement' on the government." *Id.* at 27a (quoting *Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir. 1987)).

By shifting its attention away from the statute as enacted by Congress, the court of appeals also ignored the considered judgment of the Secretary that permitting a private suit to enforce the drug ceiling price provision "would conflict with Congress's comprehensive administrative and enforcement scheme" and the Secretary's ability to administer *both* the 340B Act and the Medicaid Act on a uniform, nationwide basis. Gov't Br. at 13, 19.

As discussed, Congress implemented the 340B program using pricing metrics—AMP and BP—that it adopted unchanged from the considerably larger Medicaid rebate program. 42 U.S.C. § 256b(a) (incorporating by reference 42 U.S.C. § 1396r-8). The United States therefore explained that because "disputes over AMP and Best Price are challenges to prices reported as part of the Medicaid Rebate Program[,] plaintiff's lawsuit squarely implicates CMS's oversight of *that* program." Gov't Br. at 14 (emphasis in original). Therefore, "because AMP and Best Price affect the Medicaid Rebate Program *and* the 340B Program, allowing suits like this would threaten the orderly operation of *both* programs." *Id.* at 19 (emphasis in original).

The court of appeals departed from congressional intent in assuming that private litigants and judges

and juries were well-suited to navigate and resolve the multitude of exceedingly complex and technical issues that determine the calculation of AMP, BP, and the resulting 340B ceiling prices. *See* Gov't Br. at 4-5; 72 Fed. Reg. 39,142, 39,164 (July 17, 2007). For AMP alone, manufacturers must decide which sales, discounts, and other business arrangements to include in or exclude from the AMP pricing methodology for over 35,000 covered outpatient drugs. *See* 42 U.S.C. § 1396r-8(k)(1); Gov't Br. at 4-5.

Manufacturers devote extensive resources and expertise to getting these calculations right. "A large pharmaceutical company . . . typically has a large team of analysts, IT staff and managers devoted full-time to performing these calculations." Brown Decl. in Support of Defs.' Joint Mot. for Protective Order ¶ 5, *County of Santa Clara v. Astra USA, Inc.*, No. 05-cv-03740 (N.D. Cal. Feb. 4, 2010) ("Brown Decl."). The work involves multiple departments and trained expert employees. *See* Black Decl. in Support of Joint Mot. for Partial Judgment on the Pleadings ¶¶ 6-7, *County of Santa Clara v. Astra USA, Inc.*, No. 05-cv-03740 (N.D. Cal. Feb. 4, 2010) ("Black Decl.").

The difficulty of calculating AMP and BP has been compounded by a "lack of clear CMS guidance." Gov't Accountability Office, GAO-05-102, *Medicaid Drug Rebate Program: Inadequate Oversight Raises Concerns About Rebates Paid to States* 15 (2005). Throughout the 17 years preceding the Secretary's issuance of regulations, *see* 72 Fed. Reg. 39,142, manufacturers were guided by 79 informal "releases" that created, rather than resolved, interpretive and calculation issues. Gov't Br. at 5. For example, there was considerable confusion in the industry regarding whether administrative fees and rebates to Pharmacy

Benefit Managers (PBMs) should be included in AMP and BP. *See* Gov't Accountability Office, *supra*, at 12-15, 19-22 (explaining that "the rebate program does not clearly address certain concessions that are negotiated by PBMs on behalf of third-party payers").

In response, CMS issued Rebate Release 28:

> Best price is based on the lowest price available to any entity except those excluded under the statute or rebate agreement. Therefore, where the use of the PBM by manufacturers establishes lower prices, these lower prices should be reflected in best price calculations. . . . Drug prices to PBMs have no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement.

CMS, Medicaid Drug Rebate Program Release No. 28 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. The Government Accountability Office ("GAO"), however, was unsure from that release how PBM-negotiated manufacturer payments should be reflected in AMP and BP. *See* Gov't Accountability Office, *supra*, at 21-22. Rebate Release 29 then exacerbated the confusion by changing the last sentence to "[w]e *generally* consider drug prices to PBMs as having no effect on the AMP calculations unless the PBM is acting as a wholesaler as defined in the rebate agreement." CMS, Medicaid Drug Rebate Program Release No. 29 (1997) (emphasis added), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp.

CMS subsequently issued Rebate Release 30, announcing that "[w]e have been informed that there may have been some confusion concerning the intent

of the information published in Manufacturer Release Numbers 28 and 29 . . . . We are currently re-examining the issue and hope to clarify our position in the near future." CMS, Medicaid Drug Rebate Program Release No. 30 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. Rebate Release 30 was issued in 1997, but CMS did not issue the promised clarification until the 2007 regulations, which acknowledged "the lack of a clear definition of AMP or specific guidance regarding which retail prices should be included in AMP." 72 Fed. Reg. at 39,146.

Moreover, Congress recently altered the statutory definition of AMP. *See* Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148, § 2503, 124 Stat. 119 (2010). The Secretary accordingly withdrew the regulations governing the calculation of AMP, and advised manufacturers simply to "rely on the statutory language." Medicaid Program; Withdrawal of Determination of Average Manufacturer Price, Multiple Source Drug Definition, and Upper Limits for Multiple Source Drugs 13 (to be published Nov. 15, 2010), *available at* http://www.ofr.gov/OFRUpload/OFRData/2010-28649_PI.pdf. Until the Secretary issues further guidance, manufacturers inevitably will face considerable uncertainty with respect to the statutory drug-pricing methodology. Private suits thus could unjustifiably penalize manufacturers for the lack of agency guidance if courts (and perhaps juries) impose liability because they disagree with a manufacturer's judgments about pricing methodology.

Judicial second-guessing would also conflict with the regulatory regime to the extent it permits manufacturers to employ varying calculation methods for

AMP and BP, so long as their methodology is reasonable. Gov't Br. at 5. "[I]n the absence of specific statutory or agency guidance," the Secretary has "allowed manufacturers to make reasonable assumptions in their calculations of AMP and Best Price, consistent with the intent of 42 U.S. § 1396r-8, federal regulations, and the terms of the agreement." *Id.* (internal brackets and quotation marks omitted); *accord* J.A. 78-79 (Medicaid Rebate Agreement § II(i)); 72 Fed. Reg. at 39,171. It is wholly implausible that Congress contemplated that any of the thousands of 340B entities could require courts to sort through and perhaps second-guess the drug manufacturers' decisions with respect to millions upon millions of drug transactions to determine whether those decisions were reasonable.

2. Private suits would also conflict with Congress's decision to provide for enforcement by the Secretary. The United States correctly concluded that private suits would "undermine HHS's role" in administering and enforcing both the 340B and Medicaid programs. Gov't Br. at 13. Such suits also would "permit enforcement without the check imposed by prosecutorial discretion." *Sosa v. Alvarez-Machain*, 542 U.S. 692, 727 (2004).

And, as mentioned, the PPA permits the Secretary to initiate an informal dispute resolution process on behalf of a covered entity and, if warranted, the Secretary can require a manufacturer to reimburse a covered entity for discounts withheld. Pet. App. 174a (PPA ¶ IV(c)); *see also* 61 Fed. Reg. 65,406 (Dec. 12, 1996) (implementing a voluntary dispute resolution program). The Ninth Circuit found that only the PPA, and not the 340B Act, authorized the Secretary to enforce the 340B ceiling price. Pet. App. 26. The

court's analysis, however, ignored the interrelationship between the 340B program and the Medicaid rebate program under which drug manufacturers report to the Secretary the AMP and BP figures that are the basis for the 340B drug discounts. *See supra* p. 8.[4]

The Medicaid Act authorizes serious penalties for a manufacturer's violation of the rules governing calculation and reporting of AMP and BP. The Medicaid statute allows the Secretary to impose fines of up to $10,000 per day for failure to report AMP and BP information, and penalties of up to $100,000 per instance of knowingly providing false AMP and BP information. 42 U.S.C § 1396r-8(b)(3)(C); *see also* PPACA § 7102(a) (adding 42 U.S.C. § 256b(d)(1)(B)(vi) to impose civil monetary penalties of up to $5,000 per instance of a manufacturer knowingly and intentionally charging a covered entity a price that exceeds the 340B ceiling price). The Secretary also may terminate the Medicaid Rebate Agreement for violation of the AMP and BP reporting requirements. 42 U.S.C. § 1396r-8(b)(4)(B)(i). The Medicaid Rebate Agreement further permits the Secretary to audit a manufacturer's AMP and BP figures that underlie the 340B ceiling price and Medicaid rebate amount and, if necessary, require manufacturers to recal-

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[4] PPACA amends the 340B Act to require the Secretary to promulgate regulations to establish an administrative process to resolve covered entities' claims that manufacturers violated the PPA or the 340B Act. PPACA § 7102(a) (adding 42 U.S.C. § 256b(d)(3)). The resolution under that process "shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction." *Id.* (adding 42 U.S.C. § 256b(d)(3)(C)). The Secretary has solicited input from interested parties but has not yet proposed regulations. 75 Fed. Reg. 57,233 (Sept. 20, 2010).

culate them. J.A. 79 (Medicaid Rebate Agreement § III(c)).

3. Private rights of action also would impose unwarranted and costly administrative burdens on drug manufacturers that already devote significant resources to comply with both the 340B and Medicaid drug rebate programs. For example, the suit here does not allege *any* specific overcharge for any particular drug by any particular drug manufacturer. The complaint therefore does not identify any individual 340B entity that paid a higher price for covered drugs than required under the 340B drug ceiling price program. As the district court observed, this suit "is based largely on government reports that never identified the manufacturer, drug or 340B entity." Pet. App. 112a; *see also* Gov't. Br. at 10 ("Plaintiff did not explain why it thought it had been overcharged for any specific drug."); Pet. App. 29a ("[T]he nature of the breaches Santa Clara will seek to prove is unclear . . . .").

This suit nonetheless has forced petitioners to collect and produce confidential and sensitive drug-pricing and sales information on a national basis for millions of drug sales transactions. Pet. App. 74a-77a. The extent and quantity of the information sought by the County is breathtaking. For petitioner GlaxoSmithKline, for instance, the County sought "more than 100 million [computer] data records per quarter" that the company sorts and analyzes for its AMP and BP calculations. Brown Decl. ¶ 9. That size and scope is typical for other manufacturers as well. *See, e.g.*, Le Compte Decl. in Support of Joint Mot. for Partial Judgment on the Pleadings ¶ 5, *County of Santa Clara v. Astra USA, Inc.*, No. 05-cv-03740 (N.D. Cal. Feb. 4, 2010) ("approximately 150

million sales records" for Pfizer); Black Decl. ¶ 8 ("over 30 million sales transactions" for Wyeth).

These burdensome discovery requests violate the confidentiality provision of the Medicaid Act. The confidentiality provision provides that, "[n]otwithstanding any other provision of law, information disclosed by manufacturers . . . under [42 U.S.C. § 1396r-8(b)] . . . is confidential and shall not be disclosed by the Secretary . . . in a form which discloses the identity of a specific manufacturer . . . [or] prices charged for drugs by such manufacturer. . . ." 42 U.S.C. § 1396r-8(b)(3)(D).

The Secretary "interprets this confidentiality provision to bar her from entering into any contractual agreement that allows 340B entities to obtain discovery about AMP and Best Price calculations," and concludes that, because the confidentiality provision applies "notwithstanding any other provision of law," "it is irrelevant . . . that discovery would be compelled by court rules." Gov't. Br at 20-21. The Secretary's interpretation of the confidentiality provision is reasonable and entitled to deference. *Id.* (citing *Beck v. PACE Int'l Union*, 551 U.S. 96, 104 (2007)). Allowing private suits, and their corresponding discovery, would thus conflict with the Medicaid Act's requirement that the Secretary ensure the confidentiality of drug manufacturers' pricing and drug sales information.

Private enforcement of the 340B program also would threaten to impose conflicting obligations on drug manufacturers under both the Medicaid drug rebate and 340B ceiling price programs. Due to differences in the pricing formulas under the two statutes, changes in AMP can have opposite effects on Medicaid rebate calculations and 340B ceiling price

calculations. For example, a reduction in AMP may cause a manufacturer's Medicaid rebate payments to the States to decline (*e.g.*, because 15.1 percent of a lower AMP results in a lower rebate amount) while increasing the discount that 340B entities may receive (*e.g.*, because the AMP minus the unit rebate amount results in a lower number).

Such a decrease in Medicaid rebates would be a detriment to the States under the larger Medicaid program, yet the decrease in the 340B ceiling price simultaneously would be an advantage to a 340B entity. Thus, States, under the Medicaid program, have the opposite incentive—to maintain the higher reported AMPs, which would increase the rebates the States receive. As the United States informed the court of appeals, "if both 340B entities and states can bring separate suits over AMP calculations, there is a real possibility that manufacturers could be subject to inconsistent obligations." *Id.* at 31-32. "[B]ecause AMP and Best Price affect the Medicaid Rebate Program *and* the 340B Program, allowing suits like this would threaten the orderly operation of *both* programs" and undermine the agency's role "to resolve issues for both programs at once." *Id.* at 19, 32 (emphasis in original).

The County's argument, Br. in Opp. 34, that private suits produce a "win-win" because a lower BP generally benefits States as well as 340B entities, ignores and does not refute the government's view that States and 340B entities have conflicting incentives with respect to AMP. Gov't Br. at 31. Thus, manufacturers are placed in the untenable position of being exposed to conflicting AMP obligations depending on the identity of the plaintiff. Even with

respect to BP, private suits expose manufacturers to case-by-case determinations of the correct BP.

### E. The Federal Common Law Of Contracts Is Not A Basis To Create A Private Right To Enforce The 340B Act

1. The PPA is a federal contract to which the United States is a party, and the PPA accordingly provides that it "shall be construed in accordance with Federal common law." Pet. App. 180a (PPA ¶ VII(g)). That choice-of-law provision thus identifies federal common law, as opposed to that of any specific State, as the source of law for interpreting the document. It is well settled that federal common law principles govern the contractual obligations of the United States. *E.g.*, *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366 (1943); *Mobil Oil Expl. & Producing Se., Inc. v. United States*, 530 U.S. 604, 607 (2000).[5]

But that provision is not a license for the federal courts to create substantive rights for an entire new class of parties to whom Congress declined to grant those rights. A court's exercise of federal common law is limited by "the paramount authority of

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[5] The Ninth Circuit in a footnote stated that the court was not resolving "whether federal or state law creates the cause of action underlying [the County's] contract claim." Pet. App. 8a n.5. The court similarly noted that the 340B Act "does not preempt a state law contract cause of action, if that indeed is how [the County's] claim should be characterized." *Id.* at 24a n.16. Those statements are seriously mistaken in light of (1) the PPA's designation of federal common law as the choice of law, *id.* at 180a (PPA ¶ VII(g)), (2) the United States's status as a party to the contract, *Clearfield Trust Co.*, 318 U.S. at 366, and (3) the court of appeals's repeated invocation of "*federal* common law" to recognize a right of action by Section 340B covered entities, *see, e.g.*, Pet. App. 10a, 22a, 26a, 27a (emphasis added).

Congress." *Nw. Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95 (1981) (internal quotation marks omitted); *City of Milwaukee v. Illinois*, 451 U.S. 304, 313-14 (1981). "[T]he usual and important concerns of an appropriate division of functions between the Congress and the federal judiciary," apply equally when federal common law is implicated. *City of Milwaukee*, 451 U.S. at 313.

"There is no federal general common law." *Erie R.R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). "Federal courts, unlike state courts, are not general common-law courts and do not possess a general power to develop and apply their own rules of decision." *City of Milwaukee*, 451 U.S. at 312; *see Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 640 (1981). Thus, even when federal courts have "express congressional authorization to devise a body of [federal common] law directly," *Sosa*, 542 U.S. at 726, any substantive rights must stem from an Act of Congress.

For example, this Court in *Mertens v. Hewitt Associates*, 508 U.S. 248 (1993), held that, even though Congress authorized the development of federal common law to interpret ERISA, 29 U.S.C. § 1001 *et seq.*, federal common law could not form the basis of a private right of action to enforce ERISA for non-fiduciaries because the Act did not affirmatively authorize such a suit. *Id.* at 255 & n.5. The Court in *Texas Industries, Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630 (1981), similarly rejected a common law remedy of contribution under the Sherman Act, 15 U.S.C. § 1, because the Court found no affirmative indication that "Congress intended courts to have the power to alter or supplement the remedies enacted." *Id.* at 645. Likewise, Congress in the 340B Act

concededly did not provide for enforceable rights on behalf of 340B entities.

Further, where Congress has "occupied the field through the establishment of a comprehensive regulatory program supervised by an expert administrative agency," private remedies are limited to those enacted by Congress. *City of Milwaukee*, 451 U.S. at 317; *Middlesex Cnty. Sewerage Auth. v. Nat'l Sea Clammers Assoc.*, 453 U.S. 1, 21-22 (1981); *Nw. Airlines, Inc.*, 451 U.S. at 93-94. Thus, "once Congress addresses a subject . . . the task of the federal courts is to interpret and apply statutory law, not to create common law." *Nw. Airlines Inc.*, 451 U.S. at 95, n.34. "Although a federal court may disagree with the regulatory approach taken by the agency with responsibility . . . under the Act, such disagreement alone is no basis for the creation of federal common law." *City of Milwaukee*, 451 U.S. at 323. As discussed, private suits by 340B entities to enforce the manufacturers' drug-pricing obligations would seriously disrupt two massive, complex, and comprehensive drug-pricing programs.

2. Because Congress did not authorize a private right of action under the 340B Act, the County errs in relying on *Jackson Transit Authority v. Local Division 1285*, 457 U.S. 15 (1982), and *Clearfield Trust Co. v. United States*, 318 U.S. 363 (1943). Br. in Opp. 4-5. Those decisions address a choice of law question—whether federal or state law should govern the construction of a contract where the federal government is a party or the contract otherwise implicates federal interests. *See Boyle v. United Techs. Corp.*, 487 U.S. 500, 512 (1988) (tort action governed by federal law); *Miree v. DeKalb Cnty.*, 433 U.S. 25, 29 (1977) (third-party beneficiary action governed by

state law). Those decisions do not address the threshold validity of a private right to sue.

Moreover, the plaintiff in *Jackson* was a party to the contract, and the Court held that Congress intended that the contract be enforceable, albeit under state law. 457 U.S. at 21 ("[T]he precise question before us is whether the union's contract actions are federal causes of action, not whether the union can bring suit at all to enforce its contracts."). *Jackson* makes clear that where a statute is involved, *congressional intent* is controlling. *Id.*; *see Empire Healthchoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 694-95 (2006). No decision of this Court supports the proposition that where Congress declines to create a cause of action, a court may use federal common law to create one anyway.

## CONCLUSION

The judgment of the court of appeals should be reversed.

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# RESPONDENT'S BRIEF

No. 09-1273

IN THE
# Supreme Court of the United States

ASTRA USA, INC., ET AL.,
*Petitioners*,

v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,
*Respondent*.

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

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## QUESTION PRESENTED

Whether, where Congress elected to implement the section 340B drug discount program through federal contracts and mandated that those contracts contain a provision making 340B entities intended third-party beneficiaries, 340B entities have a federal cause of action against drug manufacturers for their breach of that contract provision absent a more specific provision conferring a right of action on 340B entities.

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*Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104 (1991) ..... 34

*Audio Odyssey, Ltd. v. United States*, 255 F.3d 512 (8th Cir. 2001)..... 32

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*Hollander v. Brezenoff*, 787 F.2d 834 (2d Cir. 1986) ..... 45

*International Ass'n of Machinists v. Central Airlines, Inc.*, 372 U.S. 682 (1963) .....25, 26, 27, 29

*Isbrandtsen Co. v. Johnson*, 343 U.S. 779 (1952) ..... 35

*Jackson Transit Auth. v. Local Div. 1285*, 457 U.S. 15 (1982) ..... 1, 19, 21, 25, 26, 27, 28, 30, 36, 38

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*Lynch v. United States*, 292 U.S. 571 (1934) ..... 44

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*Molzof v. United States*, 502 U.S. 301 (1992) ..... 30

*Montana v. United States*, 124 F.3d 1269 (Fed. Cir. 1997) ..... 34

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*Starkey v. Mill*, 82 Eng. Rep. 723 (K.B. 1651) ..... 31

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*United States v. Seckinger*, 397 U.S. 203 (1970) ..... 29

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*United States v. Winstar Corp.*, 518 U.S. 839 (1996) ..... 21, 44, 46

*United States ex rel. Johnson v. Morley Constr. Co.*, 98 F.2d 781 (2d Cir. 1938) ..... 31

*United States R.R. Retirement Bd. v. Fritz*, 449 U.S. 166 (1980) ..... 45

*Universities Research Ass'n, Inc. v. Coutu*, 450 U.S. 754 (1981) ..... 39

*Verizon Maryland Inc. v. Global NAPs, Inc.*, 377 F.3d 355 (4th Cir. 2004) ..... 26

*Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765 (2000) ..... 52

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False Claims Act, 31 U.S.C. § 3729 *et seq.* ....9, 23, 50, 52, 57, 58

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Federal Arbitration Act, 9 U.S.C. § 1 *et seq.* .....24, 35

Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) ....5, 8, 21, 41, 46, 55, 57

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§ 7102(a), 124 Stat. 826 ..... 8

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Social Security Act, 42 U.S.C. § 301 *et seq.* ..... 45

Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71 ..... 6

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42 U.S.C. § 1396r-8(b) ..... 53
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LEGISLATIVE MATERIALS

H.R. Rep. No. 101-881 (1990), *reprinted in* 1990 U.S.C.C.A.N. 2017 ..... 4, 5
H.R. Rep. No. 102-384(II) (1992) ..... 5, 6, 7, 16, 33-34

*Medicaid Budget Initiatives: Hearings Before the Subcomm. on Health and the Environment of the H. Comm. on Energy and Commerce*, 101st Cong., H. Hrg. 101-206 (1991) ..... 4

*Medicaid Prescription Drug Pricing: Hearing Before the Subcomm. on Health for Families and the Uninsured of the S. Comm. on Finance*, 101st Cong., S. Hrg. 101-1261 (1991) ..... 4

*Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency: Hearing Before the Subcomm. on Oversight and Investigations of the H. Comm. on Energy and Commerce*, 109th Cong., H. Hrg. 109-108 (2006), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf.....12, 38

*Skyrocketing Prescription Drug Prices: Hearings Before the S. Special Comm. on Aging*, 101st Cong., S. Hrg. 101-747 (1990) ..... 4

ADMINISTRATIVE MATERIALS

Advanced Notice of Proposed Rulemaking and Request for Comments, 340B Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57,233 (Sept. 20, 2010)..... 8

Congressional Budget Office, *Prices for Brand-Name Drugs Under Selected Federal Programs* (June 2005), http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf ..... 7

Dep't of Health and Human Services & Dep't of Justice Health Care Fraud and Abuse Control Program, Annual Report for FY 2003 (Dec. 2004), http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2003A.htm ..... 9

Dep't of Justice:

Press Release, *AstraZeneca Pharmaceuticals LP Pleads Guilty to HealthCare Crime; Company Agrees to Pay $355 Million to Settle Charges* (June 20, 2003), http://www.justice.gov/opa/pr/2003/June/03_civ_371.htm ..... 10

Press Release, *Aventis Pharmaceutical to Pay U.S. $95.5 Million to Settle False Claims Act Allegations* (May 28, 2009), http://www.justice.gov/opa/pr/2009/May/09-civ-520.html ..... 9

Press Release, *Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing* (Sept. 28, 2007), http://www.justice.gov/opa/pr/2007/September/07_civ_782.html ..... 9

Press Release, *Drug Giant Pfizer & Two Subsidiaries to Pay $49 Million for Defrauding Drug Medicaid Rebate Program* (Oct. 28, 2002), http://www.justice.gov/opa/pr/2002/October/02_civ_622.htm ..... 10

Press Release, *Merck to Pay More than $650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks* (Feb. 7, 2008), http://www.justice.gov/opa/pr/2008/February/08_civ_094.html ..... 10

Press Release, *Schering-Plough to Pay $345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin* (July 30, 2004), http://www.justice.gov/opa/pr/2004/July/04_civ_523.htm ..... 10

Press Release, *TAP Pharmaceutical Products Inc. and Seven Others Charged With Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges* (Oct. 3, 2001), http://www.justice.gov/opa/pr/2001/October/513civ.htm ..... 10

Final Notice, Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110 (May 13, 1994) ..... 49

Final Notice, Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406 (Dec. 12, 1996) .....8, 35, 36, 48

Government Accountability Office, Medicaid Drug Rebate Program, *Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102 (Feb. 2005), http://www.gao.gov/new.items/d05102.pdf.....13, 14, 56

Letter from Sen. Charles E. Grassley to Elizabeth M. Duke, Administrator, HRSA (Sept. 1, 2005), http://www.drugdiscountmonitor.com/members/HRSA_Letter.pdf ..... 12

Notice, Guidance Regarding Section 602 of the Veterans Health Care Act of 1002; Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27,289 (May 7, 1993) ..... 7

Office of Inspector General, Dep't of Health & Human Services:

*Appropriateness of 340B Drug Prices*, OEI-05-02-00070 (June 2004) ..... 12

*Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072 (Oct. 2005), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf ..... 12, 13, 35, 56, 57

*Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements*, OEI-03-09-00060 (Sept. 2010), http://oig.hhs.gov/oei/reports/oei-03-09-00060.pdf ..... 14, 57

*Pharmaceutical Manufacturers Overcharged 340-B-Covered Entities* A-06-01-00060 (Mar. 2003), ftp://ftp.hrsa.gov/bphc/pdf/opa/A-06-01-00060.pdf ..... 11, 12

*Review of 340B Prices*, OEI-05-02-00073 (July 2006), http://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf ..... 13, 49

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## INTRODUCTION

This case implicates a long-settled rule of law: when Congress by statute directs the making of contracts, "Congress expect[s] the . . . agreement[s] . . . , like ordinary contracts, to be enforceable by private suit upon a breach." *Jackson Transit Auth. v. Local Div. 1285*, 457 U.S. 15, 20-21 (1982). Such a private suit, moreover, will "state[] [a] federal claim[]" where Congress intended that "the rights and duties contained in those contracts be federal in nature." *Id.* at 23.

Those longstanding principles stand in stark contrast to situations where the Court is asked to imply a right of action in a statute in which Congress neither provided an express right of action nor required enforceable contracts. As this Court has made clear, cases involving federal contracts "do[] not fit comfortably in th[e] mold" of "private right of action case[s]." *Id.* at 20. Although petitioners and many of their *amici* labor to squeeze this case into the line of precedents involving "implied rights of action," an interpretation faithful to the language Congress actually used leads inexorably to the conclusion that respondent may sue to enforce petitioners' alleged breach of the statutorily mandated agreement.

Section 340B of the Public Health Service Act ("PHSA") aims to ensure that public hospitals, community health centers, and other providers of safety-net health services pay the same low prescription drug prices available to Medicaid. In effectuating that intent, Congress directed the Secretary of Health and Human Services ("HHS") to make "agreement[s]" with drug manufacturers limiting "the amount required to be paid . . . to the manufacturer" for drugs purchased by those "covered entit[ies]." 42

U.S.C. § 256b(a)(1). Each petitioner here signed a Pharmaceutical Pricing Agreement ("Agreement") with the Secretary; in the contract, each manufacturer "agree[d]" to "charge [340B] entities a price" that, for brand-name drugs, is normally no higher than the manufacturer's best price in the marketplace. Agreement § II(a) (App. 170a).

Following revelations stemming from federal investigations and court proceedings that manufacturers repeatedly had broken that promise, respondent County of Santa Clara sued on behalf of its 340B county medical facilities and a class of similarly situated entities, as intended third-party beneficiaries of each petitioner's Agreement. Common law from the 1600s establishes that contracts can be enforced by a class of third parties, and nothing in § 256b suggests that Congress displaced that ancient contractual remedy. As intended third-party beneficiaries, 340B entities "state[] a federal claim when [they] sue[] to vindicate contractual rights" in the Agreement, even though § 256b "lack[s] express provisions creating [a] federal cause[] of action." *Empire HealthChoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 694 (2006) (internal quotations omitted).

All but ignoring this Court's longstanding rulings regarding the enforcement of federal contracts, petitioners and their *amici* — except, notably, the United States — argue that the lack of an express or implied cause of action to enforce the statute is dispositive. But the fundamental flaw in that approach is that it nullifies Congress's decision to mandate that the Secretary and drug manufacturers enter into what petitioners and their industry association concede are "federal contract[s]." Pet. Br. 42; *see also id.* at i; PhRMA Br. 2, 9. On their view, § 256b is no different

from a statutory mandate, implemented through notice-and-comment rulemaking, that conditions a manufacturer's inclusion in Medicaid on its willingness to sell to 340B entities at reduced prices. But Congress instead chose to use contracts and, moreover, did not create any administrative remedy that might displace longstanding common-law contract remedies for intended third-party beneficiaries.

The United States implicitly recognizes that petitioners' reliance on this Court's implied-right-of-action jurisprudence is misplaced. Instead, it offers novel arguments outside the Question Presented that petitioners have waived and that, on their own terms, lack merit. The United States first erroneously denies that the Agreement is an enforceable contract, notwithstanding petitioners' concession that the Agreement is a contract. The United States then attempts to resuscitate an argument (waived by petitioners in the certiorari petition) that 340B entities are not intended third-party beneficiaries under the Agreement. The terms Congress mandated that the Secretary include in the Agreement clearly identify 340B entities as intended beneficiaries of manufacturers' promise to cap the prices at which they sell drugs to 340B entities, consistent with settled common-law principles.

Respondent's breach-of-contract remedy both advances Congress's design to provide the best prices to entities that serve the poor and complements federal government enforcement efforts that have been insufficient. Such parallel suits "enforce federal ... requirements" and "aid, rather than hinder, the functioning of [federal statutes]." *Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 451 (2005).

## STATEMENT

1. Although "Medicaid is the Nation's largest single purchaser of prescription drugs," before 1990 "it usually pa[id] the highest prices" for those drugs,[1] while "other large purchasers received discounts from drug manufacturers."[2] For example, Medicaid paid $29 for a bottle of Motrin that cost a typical hospital only $8 and the Department of Veterans Affairs only $5.[3] Already high prescription drug costs were growing much faster than other Medicaid expenditures.[4]

Congress found that state of affairs intolerable, not only because Medicaid's purchasing power ought to garner the best discounts available in the market, but also because Medicaid uses scarce federal and state taxpayer dollars to provide safety-net medical care to the most vulnerable individuals. Congress was concerned that States — which pay a portion of Medicaid costs — might respond to skyrocketing drug costs by curtailing Medicaid beneficiaries' access to needed medications.[5]

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[1] Melvina Ford, Congressional Research Service Report for Congress, *Medicaid: Reimbursement for Outpatient Prescription Drugs*, CRS-17 (Mar. 7, 1991) ("Ford").

[2] Ford at CRS-15; *see also* H.R. Rep. No. 101-881, at 96 (1990) ("1990 House Report"), *reprinted in* 1990 U.S.C.C.A.N. 2017; *Skyrocketing Prescription Drug Prices*, S. Hrg. 101-747 (1990); *Medicaid Budget Initiatives*, H. Hrg. 101-206 (1991); *Medicaid Prescription Drug Pricing*, S. Hrg. 101-1261 (1991).

[3] *See Skyrocketing Drug Prices* at 4; *id.* at 33-40; Ford at CRS-17.

[4] *See Pharmaceutical Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 649 n.1 (2003).

[5] *See* Ford at CRS-15.

To ensure that Medicaid has "the benefit of the best price" available in the marketplace, Congress enacted the Medicaid Rebate Program in 1990.[6] *See* 42 U.S.C. § 1396r-8.[7] Congress compelled manufacturers seeking to sell drugs to Medicaid patients to "enter[] into and have in effect a rebate agreement" with the Secretary of HHS (or, at the Secretary's discretion, with a State); that contract would require the manufacturer to rebate to States a portion of the purchase price of prescription drugs. § 1396r-8(a)(1), (b)(1)(A).[8] Only with such a contract in place would federal Medicaid funds be available to pay a portion of the States' prescription drug costs. *See* §§ 1396b, 1396r-8(a)(1).

**2.** Manufacturers responded to the new Medicaid contracts by *raising* their "'best prices' on covered outpatient drugs that Medicaid patients use in any significant volume," thereby minimizing the cost of rebates due to the States.[9] Hardest hit by those price increases were "[f]ederally-funded clinics and public

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[6] 1990 House Report at 96.

[7] Unless otherwise noted, statutory citations below are to Title 42. Congress amended both the Medicaid and 340B program statutes in the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) ("PPACA"). References herein are to the pre-PPACA Medicaid and 340B program statutes, unless otherwise noted.

[8] Congress recognized that certain larger States, like California, already had negotiated their own contracts with certain manufacturers for discounts for their state Medicaid programs. Congress preserved those contracts, so long as they provided benefits equivalent to those under the new rebate contracts. *See* § 1396r-8(a)(4).

[9] H.R. Rep. No. 102-384(II), at 9 (1992) ("1992 House Report").

hospitals serving large numbers of low-income patients."[10]

In 1992, Congress responded to manufacturers' price hikes by enacting section 340B of the PHSA, 42 U.S.C. § 256b,[11] through which it expanded both the contract regime and the best-price provisions it had adopted for Medicaid. Specifically, Congress required the Secretary to "enter into an agreement with each manufacturer" that sells drugs reimbursed by Medicaid; that contract would cap the price the manufacturer could charge to any 340B "covered entity." § 256b(a)(1). *See* 1992 House Report at 7, 12 (explaining that a specific purpose of section 340B was "to enable . . . certain Federally-funded clinics to obtain lower prices on the drugs that they provide to their patients" and that "[i]n giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services").

340B covered entities include public hospitals and community health centers that provide safety-net services, among others.[12] Such entities must take steps to prevent issuance of Medicaid rebates for drugs that manufacturers sell to 340B entities at a discount pursuant to an Agreement. *See* § 256b(a)(5). Congress directed HHS to "establish a mechanism" to enforce that prohibition; 340B entities may be "liable to the manufacturer" to refund the discount

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[10] *Id.* at 10.

[11] *See* Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, 4967-71.

[12] *See* § 256b(a)(4) (defining "covered entity").

provided under the Agreement. § 256b(a)(5)(A)(ii), (I)). Congress described that discount as having been "provided under the agreement ***between the entity and the manufacturer*** under this paragraph" — that is, under the Agreement. § 256b(a)(5)(I)) (emphasis added).

To implement the 340B program, the Secretary drafted the Agreement, which it sent to manufacturers in December 1992 for their signature. App. 165a-181a.[13] By signing the Agreement, a "[m]anufacturer agrees" to "charge covered entities a price . . . that does not exceed" a ceiling price. Agreement § II(a)-(b). For "a single source drug or innovator multiple source drug" — that is, brand-name drugs[14] — the discounted price is typically the manufacturer's "best price." The statute defines "best price" to mean the "lowest price available" in the marketplace (with certain exceptions), after accounting for any "cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates." § 1396r-8(c)(1)(C)(i); *see* Agreement § I(b).[15]

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[13] *See also* 58 Fed. Reg. 27,289, 27,291 (May 7, 1993).

[14] *See* 42 C.F.R. § 447.502 ("*Brand name drug* means a single source or innovator multiple source drug.")

[15] The minimum discount for a brand-name drug is 15.1% off the "average manufacturer price" or "AMP" of a drug, and 11% off the AMP of other drugs. *See* § 1396r-8(c)(1)(B), (c)(3)(B); Agreement § II(a)-(b). The AMP is simply the average price paid nationwide for a drug by wholesalers that distribute drugs to retail pharmacies. *See* § 1396r-8(k)(1); Agreement § I(a). In sum, "the 340B ceiling price . . . equals the Medicaid net manufacturer price." Congressional Budget Office, *Prices for Brand Name Drugs Under Selected Federal Programs* 12 (June 2006), http://www.cbo.gov/ftpdocs/70xx/doc7081/06-16-PrescriptDrug.pdf

As enacted, section 340B contained no administrative dispute resolution process — informal or otherwise — although Congress authorized the Secretary to terminate an Agreement "for violation of the requirements of the agreement." § 1396r-8(b)(4)(B)(i), (v). The Agreement, however, provides that the Secretary "may initiate [an] informal dispute resolution process" if it "believes that the Manufacturer" has breached the Agreement, through which the Secretary "may require the Manufacturer to reimburse [a covered] entity for discounts withheld." Agreement § IV(c). The Agreement provides that this informal process does not "preclude . . . the Secretary from exercising such other remedies as may be available by law" to remedy a breach of the Agreement. *Id.* § IV(e). HHS also has a generally applicable informal dispute process, but similarly has made clear that "[n]o manufacturer or covered entity is required to avail itself of" that process "before resorting to other available measures." 61 Fed. Reg. 65,406, 65,411 (Dec. 12, 1996).[16]

**3.** Despite the plain terms of their Medicaid contracts and the Agreement, drug manufacturers repeatedly have overcharged 340B entities and Medi-

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[16] Congress recently amended § 256b to require the Secretary to establish a formal dispute resolution process for sales to covered entities on or after January 1, 2010. *See* PPACA §§ 7101(e), 7102(a), 124 Stat. 823, 826 (codified at § 256b(d)(3)). Congress directed the Secretary to "promulgate regulations" to create this administrative process within 180 days — or by September 19, 2010. *Id.* § 7102(a), 124 Stat. 826 (codified at § 256b(d)(3)(A)). The Secretary did not meet that deadline. Instead, on September 20, 2010, the Secretary issued an advanced notice of proposed rulemaking seeking comment on 13 areas to inform its development of proposed regulations. *See* 75 Fed. Reg. 57,233 (Sept. 20, 2010).

caid by disguising the best prices for their brand-name drugs. Those schemes have come to light through whistleblower complaints filed under the False Claims Act ("FCA").

In one scheme — known as "lick and stick" — drug manufacturers sold heavily discounted drugs to health maintenance organizations, which resold the drugs at retail under a private label. Manufacturers excluded those re-branded discounted sales from the best prices reported to HHS. Following disclosure by a whistleblower of one such "lick and stick scheme," petitioner Bayer settled FCA charges and pleaded guilty to criminal charges, paying $257 million.[17] Whistleblower suits likewise caused petitioners GlaxoSmithKline to pay $87 million,[18] Bristol-Myers Squib to pay $515 million, and Aventis to pay $95.5 million, in whole or in part to settle claims based on similar schemes.[19] Only a small portion of those settlement dollars went to reimburse 340B entities that overpaid those manufacturers.

In another scheme, manufacturers provided purchasers with "off-invoice price concessions" — or kickbacks — tied directly to the purchase of the drugs. Manufacturers, however, excluded the value

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[17] HHS/DOJ Health Care Fraud and Abuse Control Program, *Annual Report for FY 2003* (Dec. 2004), http://oig.hhs.gov/publications/docs/hcfac/hcfacreport2003A.htm.

[18] *See id.*

[19] *See* DOJ Press Release, *Bristol-Myers Squibb to Pay More Than $515 Million to Resolve Allegations of Illegal Drug Marketing and Pricing* (Sept. 28, 2007), http://www.justice.gov/opa/pr/2007/September/07_civ_782.html; DOJ Press Release, *Aventis Pharmaceutical to Pay U.S. $95.5 Million to Settle False Claims Act Allegations* (May 28, 2009), http://www.justice.gov/opa/pr/2009/May/09-civ-520.html.

of those concessions (including cash, grants, and trips, among others) in calculating the best prices for those drugs.[20] Again, whistleblowers revealed these schemes, which led to guilty pleas, settlements, and payments by petitioners TAP Pharmaceuticals of $875 million, Merck of $650 million, AstraZeneca of $355 million, Schering-Plough of $345 million, and Pfizer of $49 million.[21] And, again, 340B entities received little of that money.

In still another scheme, manufacturers have sought to evade the Agreement provision pertaining to bundled sales, which requires the manufacturer to allocate the discounts provided on each drug across all drugs in the bundle. *See, e.g.*, Agreement § I(a), (c). Manufacturers repeatedly have excluded contracts offering bundles of drugs in calculating their best prices. Following whistleblower revelations, the United States and more than 30 States currently are pursuing claims for hundreds of millions of dollars

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[20] DOJ Press Release, *AstraZeneca Pharmaceuticals LP Pleads Guilty to HealthCare Crime; Company Agrees to Pay $355 Million to Settle Charges* (June 20, 2003), http://www.justice.gov/opa/pr/2003/June/03_civ_371.htm.

[21] *See id.*; DOJ Press Release, *TAP Pharmaceutical Products Inc. and Seven Others Charged With Health Care Crimes; Company Agrees to Pay $875 Million to Settle Charges* (Oct. 3, 2001), http://www.justice.gov/opa/pr/2001/October/513civ.htm; DOJ Press Release, *Schering-Plough to Pay $345 Million to Resolve Criminal and Civil Liabilities for Illegal Marketing of Claritin* (July 30, 2004), http://www.justice.gov/opa/pr/2004/July/04_civ_523.htm; DOJ Press Release, *Drug Giant Pfizer & Two Subsidiaries to Pay $49 Million for Defrauding Drug Medicaid Rebate Program* (Oct. 28, 2002), http://www.justice.gov/opa/pr/2002/October/02_civ_622.htm; DOJ Press Release, *Merck to Pay More than $650 Million to Resolve Claims of Fraudulent Price Reporting and Kickbacks* (Feb. 7, 2008), http://www.justice.gov/opa/pr/2008/February/08_civ_094.html.

against petitioner Wyeth for failing to include bundled sales in calculating the best price of its drug Protonix,[22] which brought in revenues of nearly $2 billion in 2007.[23]

**4.** Federal administrative efforts to rectify manufacturers' violations of their best-price duties have been virtually non-existent. The HHS Office of the Inspector General ("OIG") repeatedly has found that neither the Health Resources and Services Administration ("HRSA"), which administers the 340B program, nor the Centers for Medicare & Medicaid Services ("CMS"), which administers the Medicaid Rebate Program, has the staff or budget necessary to ensure that manufacturers comply with the terms of the Agreement with respect to the 35,000 drugs (*see* Pet. Br. 34) covered under the Agreement.

For example, a March 2003 OIG report found that, in 1998 and 1999, five manufacturers had used "lick and stick" schemes to overcharge 340B entities by $6.1 million on only $13.7 million of sales.[24] Despite HRSA's commitment to take action against these

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[22] *See, e.g.*, Complaint, *United States ex rel. Kieff v. Wyeth*, Nos. 03-12366-DPW & 06-11724-DPW (D. Mass. filed May 18, 2009); Amended Complaint of the States and the District of Columbia, *United States ex rel. Kieff v. Wyeth*, Nos. 03-12366-DPW & 06-11724-DPW (D. Mass. filed Oct. 9, 2009).

[23] *See* Wyeth 2007 Financial Report at 65, http://sec.gov/Archives/edgar/data/5187/000119312508042780/dex13.htm.

[24] *See* OIG, *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, A-06-01-00060, at 1, 3-4 (Mar. 2003), ftp://ftp.hrsa.gov/bphc/pdf/opa/A-06-01-00060.pdf.

manufacturers,[25] nearly three years later, overcharged 340B entities still were waiting for refunds.[26]

A June 2004 OIG report, later withdrawn because of problems with CMS and HRSA data, concluded that covered entities had overpaid $41.1 million in a single month.[27] In September 2005, Senator Charles Grassley, then-Chairman of the Senate Finance Committee, wrote to HRSA expressing concern, based in part on the OIG reports, with "systemic problems in the 340B program."[28]

An October 2005 OIG report similarly identified "systemic problems with the accuracy and reliability of the Government's record of the 340B ceiling price," including the fact that neither CMS nor HRSA had "established written procedures . . . for calculating the 340B ceiling price."[29] OIG also found that "no one has engaged in" HRSA's "voluntary process for resolving disputes between manufacturers and

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[25] *Id.* App. A.

[26] *See Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency*, H. Hrg. 109-108, at 17 (2006) ("*2006 Oversight Hearing*") (prepared statement of Dennis Williams, Deputy Administrator, HRSA), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf.

[27] *See* OIG, *Appropriateness of 340B Drug Prices*, OEI-05-02-00070, at 5 (June 2004) (C.A. E.R. 74-102); Withdrawal Notice (Oct. 21, 2004), http://www.oig.hhs.gov/oei/reports/oei-05-02-00070.pdf.

[28] Letter from Sen. Charles E. Grassley to Elizabeth M. Duke, Administrator, HRSA at 2-4 (Sept. 1, 2005), http://www.drugdiscountmonitor.com/members/HRSA_Letter.pdf.

[29] OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, at ii, 10, 12 (Oct. 2005) ("2005 Deficiencies Report"), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf.

[340B] entities."[30] Indeed, even where HRSA analysts discovered that manufacturers were charging prices greater than the ceiling price, "HRSA did not initiate the dispute resolution process or take other action to resolve this issue."[31]

Although the October 2005 OIG report did not "review CMS's oversight of [the] manufacturer-reported prices" used to calculate the best prices available to both Medicaid and 340B entities,[32] a February 2005 Government Accountability Office ("GAO") report had found that CMS was conducting only "minimal oversight" of "manufacturer-reported prices."[33] GAO determined that "CMS does not generally check to ensure that manufacturers' assumptions and price determination methods are consistent with the rebate statute and rebate agreement."[34] Moreover, "CMS does not verify" that manufacturers comply with their obligation to "maintain [the] documentation underlying" the reported average manufacturer prices ("AMPs") and best prices, and "rarely requests" that information from manufacturers.[35] Although the GAO report recommended that CMS implement

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[30] *Id.* at 16.

[31] *Id.* at 17. In a July 2006 report, the OIG found evidence that manufacturers had overcharged a group of 340B entities a total of $3.9 million in a single month. *See* OIG, *Review of 340B Prices*, OEI-05-02-00073, at 11 (July 2006) ("2006 Overcharge Report"), http://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf.

[32] 2005 Deficiencies Report at 8; *see id.* at 4-5.

[33] GAO, Medicaid Drug Rebate Program, *Inadequate Oversight Raises Concerns about Rebates Paid to States*, GAO-05-102, at 10 (Feb. 2005) ("2005 Inadequate Oversight Report"), http://www.gao.gov/new.items/d05102.pdf.

[34] *Id.* at 11.

[35] *Id.*

"systematic oversight" of manufacturer-reported prices,[36] a September 2010 OIG report found that CMS still "do[es] not currently have the resources to pursue" manufacturers that submit incomplete pricing reports, let alone to request (or to review) the contracts, invoices, and other documents needed to verify manufacturers' reported best prices.[37]

**5.** Respondent County of Santa Clara owns, operates, and provides health services through numerous county medical facilities that are 340B entities. *See* JA28-30 (¶ 1) ("Complaint"). Like all California counties, Santa Clara is required to act as the healthcare "'provider of last resort'" to its indigent residents. JA34 (¶ 13) (quoting Cal. Welf. & Inst. Code § 17000). From 2003 through 2005, Santa Clara's 340B entities spent approximately $90 million on drugs sold under the Agreement. *See* JA30, 45-47 (¶¶ 3, 46).

Relying on the revelations of manufacturer overcharges detailed above, Santa Clara brought suit on behalf of its 340B entities[38] and a class of similarly situated entities, alleging that the petitioner drug manufacturers have charged them more than the 340B ceiling price for covered drugs. *See* JA28-32, 47-56 (¶¶ 1, 4-7, 47-71).[39] Santa Clara's complaint raised several claims, but the single claim before this

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[36] *Id.* at 23.

[37] OIG, *Drug Manufacturers' Noncompliance With Average Manufacturer Price Reporting Requirements*, OEI-03-09-00060, at 14 (Sept. 2010) ("2010 Noncompliance Report"), http://oig.hhs.gov/oei/reports/oei-03-09-00060.pdf.

[38] The County's 340B entities lack independent authority to sue under state law. *See* App. 104a.

[39] The petitioner drug manufacturers' annual sales range from $5.8 billion to $16.5 billion. *See* JA35-40 (¶¶ 16-26).

Court is for petitioners' breach of the Agreement with the Secretary. *See* JA63-64 (¶¶ 101-104). Santa Clara alleges that it is an intended third-party beneficiary of those contracts, in which petitioners each agreed, "[p]ursuant to requirements under section 340B," "to charge covered entities a price for each unit of the drug that does not exceed [the ceiling price]." Agreement § II(a).[40]

The district court found that 340B entities are intended third-party beneficiaries under the Agreement, because the Agreement (as § 256b requires) compels manufacturers to provide discounts to 340B entities, thus "suggest[ing] that Congress intended to benefit them directly." App. 117a. The court, however, held that even an intended third-party beneficiary cannot sue to enforce a contract without an affirmative indication authorizing such a suit. *Id.* Not finding such a statement in the Agreement or the statute, the court dismissed Santa Clara's contract claim.

**6.** On appeal, the Ninth Circuit reversed. "Applying the federal common law of contracts," the court of appeals first agreed with the district court that 340B entities "are intended direct beneficiaries of the[] [Agreement]." App. 31a. The court recognized that "[d]emonstrating third-party beneficiary status in the context of a government contract is a comparatively difficult task" because "parties that benefit from a government contract are generally assumed to be incidental beneficiaries," which normally may not

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[40] Plaintiffs sought leave to move for certification of a nationwide class, which the district court denied without prejudice as premature. *See* Third Amended Case Management Order at 4 (Dkt. Entry 667).

sue to enforce the contract. App. 38a (internal quotations and alteration omitted).

In finding that 340B entities are intended, not incidental, beneficiaries under the Agreement, the Ninth Circuit reasoned that "Manufacturers undertook a specific responsibility to the covered entities: 'Pursuant to [§ 256b], the Manufacturer *agrees* . . . to charge *covered entities* a price for each unit of the drug that does not exceed' the ceiling price of that drug. *See* [Agreement] § II(a) (emphasis added)." App. 41a; *see* App. 41a-42a (reading § II(a) as "an unambiguous, concrete limitation on how much the Manufacturers may charge the covered entities"). The court concluded that, on "a fair reading of the [Agreement], we are unable to discern any substantial purpose of the [Agreement] *other* than to grant eligible covered entities a discount on covered drugs." App. 42a-43a.

The court found support for its conclusion that 340B entities are the intended beneficiaries of this provision in the legislative history, which makes clear that Congress enacted § 256b "'to *enable* . . . *certain Federally-funded clinics [i.e., covered entities] to obtain lower prices* on the drugs that they provide to their patients'" and "'to *enable these entities* to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.'" App. 43a-44a (quoting 1992 House Report at 7, 12) (emphasis and alterations by the court).

The Ninth Circuit disagreed with the district court's conclusion that something more was needed for 340B entities to sue to enforce the Agreement. Rather, "the right to sue inheres in one's status as an intended beneficiary." App. 39a (citing, *inter alia*,

Restatement (Second) of Contracts § 304 (1981) ("Restatement") ("A promise in a contract creates a duty in the promisor to any intended beneficiary to perform the promise, and the intended beneficiary may enforce the duty.")).

The court next rejected petitioners' contention that the absence of a private, statutory right of action to enforce § 256b precluded 340B entities from suing to enforce the contracts. App. 50a-55a.[41] The court, however, recognized that the correct question is whether Congress, by statute, had "displace[d]" the "federal common law contract remedy that the covered entities could invoke as intended beneficiaries of the [Agreement]." App. 51a, 54a. Reviewing the statute, the court found "[n]othing" to "suggest[] that Congress intended" to displace that common-law contract remedy; instead, such suits are "wholly compatible with the Section 340B program's objectives." App. 54a-55a. Petitioners did not petition for certiorari from the Ninth Circuit's 2008 decision.

**7.** On remand, Santa Clara sought discovery of information necessary to verify the manufacturers' reported best prices of their brand-name drugs, as such information is not publicly available and, as GAO and OIG had found, is rarely (if ever) disclosed to HHS. The manufacturers moved for a protective order, relying on a sentence in part of the Ninth Circuit's discussion of primary jurisdiction stating that the Agreement entitles 340B entities only "to the average manufacturer price *reported* to the Secretary; they cannot claim that the reported figure was itself somehow erroneous." App. 57a. The district

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[41] Santa Clara conceded below that there is no federal private right of action pursuant to § 256b, which the court of appeals assumed without deciding. *See* App. 50a & n.15.

court reluctantly issued the protective order, stating that, but for the Ninth Circuit's statement, it "would be inclined" to order the requested discovery. App. 90a. It reasoned that, to comply with the Agreement, manufacturers had to charge a price that did not exceed a ceiling price calculated using correctly reported best-price and AMP information. App. 91a.

The district court *sua sponte* certified its ruling for interlocutory appeal, which the Ninth Circuit accepted. App. 2a n.**. After receiving briefs from the parties, the Ninth Circuit sought the views of the United States as *amicus curiae*. The United States agreed with the district court that the contract required manufacturers to charge no more than a ceiling price calculated "using only accurately reported" best prices and AMPs. U.S. C.A. Amicus Br. 17 (Oct. 27, 2009). The United States nevertheless supported the district court's ruling, asserting that 340B entities should not be permitted to sue as intended third-party beneficiaries. *See id.* at 17-21. In the event the district court were reversed, however, the United States argued that the court of appeals "should refrain from invoking primary jurisdiction now," explaining that, "if any overcharging resulted from purely mechanical errors, or certain obvious and intentional fraud, the issues would not be sufficiently complex to require referral to HHS." *Id.* at 13-14; *see id.* at 25 ("No special agency expertise is implicated by such straightforward claims.").

Rather than proceed to argument and decision on the interlocutory appeal, the Ninth Circuit recalled the mandate on its original opinion. The court issued a superseding opinion, in which it altered only its discussion of primary jurisdiction. In the revised opinion, the court deleted the sentence on which the

manufacturers had relied to oppose discovery and noted that any primary jurisdiction referral was premature. *See* App. 28a-29a.

**8.** Following the Ninth Circuit's revised ruling, respondent began to obtain discovery into the manner in which petitioners calculated the best prices they reported to HHS. The district court exercised significant supervision over that discovery, limiting the initial phase to certain categories of information and depositions. *See* App. 74a-78a. As a result, the case has been pared down to a separate trial against each defendant, involving their top three to five drugs. After this Court granted the certiorari petition, the district court stayed the case, suspending the discovery (virtually all of which has been produced pursuant to a protective order) that had been proceeding into the information necessary to prove that petitioners have breached the Agreement by charging 340B entities more than the best prices for brand-name drugs.

## SUMMARY OF ARGUMENT

**I.A.** Congress required the Secretary and manufacturers to enter an "agreement" to implement § 256b. That Agreement is an enforceable federal contract. This Court's longstanding precedents establish that, when Congress employs contracts as the means of effectuating a statute, it intends for those agreements, "like ordinary contracts, to be enforceable by private suit upon a breach," regardless of the proper forum for such claims. *Jackson Transit*, 457 U.S. at 20-21. For nearly a century, this Court has held "that a plaintiff state[s] a federal claim when he sue[s] to vindicate contractual rights *set forth by federal statutes*, [even though] the relevant statutes lacked express provisions creating federal causes of

action." *Empire HealthChoice*, 547 U.S. at 694 (internal quotations omitted; emphasis and third alteration in original). Here, respondent's claim that petitioners violated the Agreement's ceiling price states a federal-law claim, both because the Agreement is a "federal contract," Pet. Br. 42, and because the United States is a party to the contract.

**B.** In selecting contracts as its mechanism for implementing § 256b and benefiting 340B entities, Congress evinced no intent to depart from standard common-law contract principles. For more than 350 years, those common-law principles have authorized certain third-party beneficiaries (now known as intended beneficiaries) to sue to enforce a contractual promise made by a party to the contract for the intended beneficiary's special benefit. As both courts below found, 340B entities are intended third-party beneficiaries of the congressionally mandated Agreement provision requiring manufacturers to "charge *covered entities* a price . . . that does not exceed" the ceiling price. Agreement § II(a) (emphasis added). The statutory text also contains Congress's reference to the Agreement as one "between the [340B] entity and the manufacturer," § 256b(a)(5)(D), and the legislative history supports the conclusion that 340B entities are intended beneficiaries of the Agreement. Only in 2010 — well after respondent's suit was brought — did Congress enact a statutory remedy that could be thought to displace the standard common-law remedy available to intended third-party beneficiaries.

**II.** Neither petitioners nor the United States provide a basis for ignoring Congress's decision to implement § 256b through enforceable contracts.

**A.** Petitioners and their *amici* — except for the United States — erroneously rely on this Court's implied private right of action cases. As this Court has concluded, cases such as this one, which seek to enforce provisions in a federal contract, "do[] not fit comfortably in th[e] mold" of "private right of action case[s]." *Jackson Transit*, 457 U.S. at 20. Indeed, under petitioners' theory, § 256b is no different from a statute that requires discounts to covered entities through statutory directives and agency notice-and-comment rulemaking. Under petitioners' reading, Congress's decision to implement § 256b through federal contracts was a completely meaningless legislative choice.

**B.** The United States alone asserts that the Agreement is not a contract because it implements a regulatory scheme. That claim is both outside the scope of the Question Presented and unpersuasive. A four-Justice plurality rejected a similar attempt to distinguish "regulatory" contracts from other contracts, explaining that such a distinction "would flout the general principle that, when the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals." *United States v. Winstar Corp.*, 518 U.S. 839, 895 (1996) (plurality) (internal quotations and alteration omitted). The authorities on which the United States relies show only that Congress's intent is highly relevant to the interpretation of contracts mandated by statute. None holds that such contracts are unenforceable through traditional, well-settled contractual remedies. The United States also erroneously seeks to read the 2010 enactment of the PPACA as evidence of Congress's intent in 1992. This Court

long has made clear that such subsequent enactments shed no light on the intent of a previous Congress.

**C.** Despite petitioners' waiver of the argument, the United States challenges respondent's status as an intended third-party beneficiary of the Agreement. But the United States' focus on whether the *Secretary* intended to permit 340B entities to sue to enforce manufacturers' promise in the Agreement is misplaced. The relevant intent is that of *Congress*, which mandated that the Secretary draft a contract requiring manufacturers to promise to charge 340B entities no more than the ceiling price. Under long-settled contract-law principles, such a provision gives rise to a federal cause of action by 340B entities to enforce that promise as intended third-party beneficiaries.

**III.A.** Suits by 340B entities are fully compatible with federal enforcement efforts, as they seek to enforce the same promises manufacturers made in signing the Agreement. As the United States has emphasized in previous cases, courts are well-suited to adjudicate claims that a manufacturer has breached its obligations with respect to drug prices. In addition, primary jurisdiction referrals to the agency are available where necessary, although many cases of best-price manipulation, such as those revealed previously through whistleblower suits, will not require the agency's special expertise.

Moreover, as the United States elsewhere has explained, it would be "unreasonable" to place on the Secretary "sole responsibility for monitoring best price fraud." U.S. Amicus Br. at 14, *In re Pharm. Indus. Average Wholesale Price Litig.*, No. 01-CV-12257-PBS (D. Mass. filed Mar. 18, 2004)

("U.S. *Mass.* Amicus Br."). HHS neither receives nor reviews the sales contracts and other documents that would reveal manufacturers' improper exclusion of rebranded sales, kickbacks, or bundled discounts from reported best prices. Thus, it makes no sense to assert, as the United States does here, that Congress intended HHS to be the exclusive enforcer of compliance with the Agreement, particularly when drug manufacturer breaches of the best-price provision directly injure 340B entities.

**B.** As myriad government reports have found, HHS is ill-equipped to enforce the best-price requirement in the Agreement and, when presented with solid evidence of violations, often has failed to remedy them. Indeed, although petitioners and the United States point to actions HHS "may" take to remedy manufacturer overcharges, they identify no actions HHS actually has taken to protect 340B entities and the public fisc. Indeed, the primary means of enforcement to date have been whistleblowers' suits under the False Claims Act. But waiting for employee whistleblowers to file *qui tam* suits is hardly a reliable means of enforcing the Agreement. Such suits rest on the fortuity of an internal watchdog who can ferret out evidence of fraudulent intent in sales reflecting alleged overpayments by 340B entities. Those 340B entities — which Congress intended to benefit and which are directly affected by manufacturer overcharges — are well-situated to enforce the Agreement. Actions by such entities complement federal enforcement efforts and enable 340B entities to stretch scarce resources farther in providing needed medicine to the poor.

## ARGUMENT

### I. CONGRESS'S DECISION TO IMPLEMENT § 256B THROUGH FEDERAL CONTRACTS THAT CREATE THIRD-PARTY BENEFICIARY RIGHTS GIVES 340B ENTITIES A FEDERAL CAUSE OF ACTION TO ENFORCE THE AGREEMENT

#### A. A Federal Contract Is Enforceable Through A Federal Cause Of Action Regardless Of Whether A Statute Provides A Private Right Of Action

1. Section 256b(a)(1) requires an "agreement" and thus plainly contemplates an enforceable contract. "In determining whether a law tenders a contract to a citizen, it is of first importance to examine the language of the statute." *Dodge v. Board of Educ.*, 302 U.S. 74, 78 (1937). Where, as here, the statutory language "provides for the execution of a written contract on behalf of the state, the case for an obligation binding upon the state is clear." *Id.* Congress's use of "agreement" in § 256b is synonymous with "contract," because the "agreement" between the Secretary and manufacturers is supported by the mutual assent and consideration required to create an enforceable contract. *See Grafton v. Cummings*, 99 U.S. 100, 110 (1878) ("agreement . . . signif[ies] a mutual contract on consideration between two or more parties"). This Court has treated "contract" and "agreement" as interchangeable terms. *See Rent-A-Center, West, Inc. v. Jackson*, 130 S. Ct. 2772, 2776-77 (2010) (using "agreement" and "contract" interchangeably in discussing Federal Arbitration Act); *see also* Restatement § 1 cmt. a (describing "agreement" and "contract" as "synonym[s]").

For nearly a century, this Court has held repeatedly "'that a plaintiff state[s] a federal claim when he sue[s] to vindicate contractual rights *set forth by federal statutes*, [even though] the relevant statutes lacked express provisions creating federal causes of action.'" *Empire HealthChoice*, 547 U.S. at 694 (quoting *Jackson Transit*, 457 U.S. at 22) (emphasis and third alteration in original). In *American Surety Co. v. Schultz*, 237 U.S. 159 (1915), for example, this Court considered whether a third party's breach-of-contract claim on a supersedeas bond stated a federal cause of action, where a federal statute required posting of the bond before pursuing a federal court appeal. The Court explained that "there would seem to be no doubt on the subject" because "the measure of . . . recovery [on the bond] depended upon the construction to be given the Federal statute." *Id.* at 160-61.

In recent decades, this Court has reaffirmed the longstanding principle that congressional statutes directing the formation of contracts evince the requisite intent for such contracts to be enforceable in private actions. In *International Association of Machinists v. Central Airlines, Inc.*, 372 U.S. 682 (1963), for example, the Court construed 45 U.S.C. § 184, in which Congress had compelled air carriers to enter into "agreement[s]" with their unionized employees to implement congressional policy regarding the settlement of employee grievances. *Id.* at 690. Finding such agreements "legally enforceable in the [federal] courts," the Court reasoned that the union's action alleging the breach of one such contract stated a federal claim, as "[t]he contracts and the adjustment boards for which they provide are creations of federal law and bound to the statute and its policy." *Id.* at

690, 692. Because the "contract[] is a federal contract [it] is therefore governed and enforceable by federal law, in the federal courts." *Id.*[42]

Similarly, in *Norfolk & Western Railway Co. v. Nemitz*, 404 U.S. 37 (1971), this Court affirmed the Sixth Circuit's ruling that railway employees had a federal cause of action to enforce a contract between two merging railroads and their employees' unions. In 49 U.S.C. § 5(2)(f) (1970), Congress had required the Interstate Commerce Commission to review and approve that contract before authorizing the merger. *See id.* at 40-43 (affirming 436 F.2d 841 (6th Cir. 1971)). And in *Transamerica Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11 (1979), the Court concluded that, by declaring in 15 U.S.C. § 80b-15 that certain contracts "shall be void," Congress "intended that the customary legal incidents of voidness would follow, including the availability of a suit for rescission or for an injunction against continued operation of the contract, and for restitution." *Id.* at 19. The Court therefore found that a suit to void such a contract stated a federal claim, *see id.* at 18, even though "the statute itself made no express provision for private suits," *Jackson Transit*, 457 U.S. at 22 (describing *Transamerica*).

This Court also repeatedly has found it appropriate to assume that Congress "expected the [statutory] agreement . . . , like [an] ordinary contract[], to be

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[42] *See also Verizon Maryland Inc. v. Global NAPs, Inc.*, 377 F.3d 355, 364-65 (4th Cir. 2004) (relying on *Central Airlines* to hold that action to enforce contract mandated by 47 U.S.C. §§ 251-252 states federal claim, where such contracts are "the vehicles chosen by Congress to implement the duties imposed in § 251" and the "specific duty" in the contract claimed to be breached "ha[s] a direct connection to the Act").

enforceable by private suit upon a breach." *Id.* at 20-21; *see Mobil Oil Exploration & Producing S.E., Inc. v. United States*, 530 U.S. 604, 607 (2000) ("When the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals.") (internal quotations omitted); *Transamerica*, 444 U.S. at 19 (Congress "intend[s] that the customary legal incidents of [contracts] follow").

Accordingly, where Congress "intended" that statutorily required "agreements be 'creations of federal law'" and that the "rights and duties contained in those contracts be federal in nature," a suit to enforce such a contract "states [a] federal claim[]." *Jackson Transit*, 457 U.S. at 23 (quoting *Central Airlines*, 372 U.S. at 692, 695).

**2.** The proposition that congressionally mandated contracts are enforceable through private actions is so well-settled that, in recent cases, the issue before this Court has been whether such actions can be pursued in federal or state forums. *Jackson Transit* thus involved a union's claim that a local transit authority had breached a contract that Congress required the authority to sign in order to receive federal funds. *See* 457 U.S. at 16-18 (discussing 49 U.S.C. § 1609(c) (1982)). Relying on the legislative history, because the "bare language of [the statute] is not conclusive," *id.* at 23, the Court found that Congress had intended for the contracts to "ensur[e] that state law preserved [transit workers'] rights" and did not intend "to create a body of federal law" enforceable in federal court, *id.* at 27-28.

In *Empire HealthChoice*, this Court also acknowledged a cause of action to enforce a congressionally mandated contract, albeit under state law. That case

involved a health insurer's suit to enforce against an insured the reimbursement provision in its contract with the Office of Personnel Management. *See* 547 U.S. at 682, 683-85. Relying on *Jackson Transit*, the insurer and the United States argued that the insurer had a *federal* cause of action to enforce its federal contract. *See id.* at 693. The Court rejected that argument, holding that the claim arose under state law. The Court reasoned that the insurer's reimbursement right was found only in the contract, whereas the statute's "text itself contains no provision addressing the reimbursement . . . rights of carriers." *Id.* at 696-97. The four dissenting Justices, however, would have held that the insurer's claim "arises under federal common law" because the claim "concerns the application of terms in a federal contract." *Id.* at 706 (Breyer, J., dissenting).

In neither case, however, was there any dispute about *whether* the plaintiff had a cause of action to enforce the statutorily mandated contract; the only question was "the proper forum" for the claim. *Id.* at 682. Indeed, in *Jackson Transit*, the Court noted that the "union, *of course*, can pursue a contract action in state court," explaining that "it is reasonable to conclude that Congress expected the [statutory] agreement . . . , like [an] ordinary contract[], to be enforceable by private suit upon a breach." 457 U.S. at 20-21, 29 n.13 (emphasis added). The Court cited with approval *Local Division 732 v. Metropolitan Atlanta Rapid Transit Authority*, 667 F.2d 1327 (11th Cir. 1982), which similarly held that "there is no question but that there is a private cause of action for breach of [the] agreement," *id.* at 1333.

**3.** Thus, the issue presented in past cases was not *whether* the contract was enforceable, but *where*

Congress intended such contracts to be litigated — as *federal* causes of action or state-law claims.

Here, petitioners correctly concede that the Agreement "is a federal contract" and that § 256b "is the source of the contractual term allegedly breached." Br. 21, 42 & n.5. This case is thus squarely within *Central Airlines*, in which the Court held that Congress "intended the statutory command" to enter an "agreement" to "be legally enforceable" through a breach-of-contract action in federal court. 372 U.S. at 690; 45 U.S.C. § 184. As *Central Airlines* stressed, where Congress mandates creation of a contract and specifies the terms of certain provisions in that contract, such provisions are "governed and enforceable by federal law, in the federal courts." 372 U.S. at 692. Notably, petitioners neither cite nor discuss *Central Airlines*. Yet their discussion (at 21-25) of the Agreement's incorporation of the statutory command that manufacturers charge covered entities no more than the ceiling price (including by best-price calculations) pursuant to statutory standards confirms that the contract mandated by Congress creates federal rights enforceable in federal court.

Federal law also independently "controls the interpretation of the contract" because the United States "entered [the Agreement] pursuant to authority conferred by federal statute." *United States v. Seckinger*, 397 U.S. 203, 209-10 (1970); *see also Boyle v. United Techs. Corp.*, 487 U.S. 500, 504 (1988) ("[O]bligations to and rights of the United States under its contracts are governed exclusively by federal law."); *United States v. Allegheny County*, 322 U.S.

174, 183 (1944); *Clearfield Trust Co. v. United States*, 318 U.S. 363, 366 (1943).[43]

### B. As Intended Third-Party Beneficiaries Of A Federal Contract, 340B Entities Have A Federal Cause Of Action To Enforce The Agreement

In selecting contracts as the means of implementing its determination that 340B entities should benefit by obtaining the same best prices available under Medicaid, Congress evinced no intent to depart from standard common-law contract principles, which include a cause of action in the event of a breach. *See Beck v. Prupis*, 529 U.S. 494, 500-01 (2000) (finding that Congress, in using a common-law concept, intended to adopt "'the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed. In such case, absence of contrary direction may be taken as satisfaction with widely accepted definitions, not as a departure from them.'") (quoting *Morissette v. United States*, 342 U.S. 246, 263 (1952)); *see also United States v. Wells*, 519 U.S. 482, 491 (1997); *Molzof v. United States*, 502 U.S. 301, 307 (1992); *NLRB v. Amax Coal Co.*, 453 U.S. 322, 329 (1981).

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[43] In all events, as the Ninth Circuit held (*see* App. 8a-9a n.5), even if Santa Clara's breach-of-contract claim were a state-law claim, that claim still would arise under federal law under *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308, 314 (2005). And, even if that claim were found not to arise under federal law, it would be enforceable in state court, as were the contracts at issue in *Empire HealthChoice* and *Jackson Transit*. *See supra* pp. 27-28.

1. A bedrock principle of the common law of contracts — dating back to English cases sounding in *assumpsit* — is that a class of third parties (now known as intended third-party beneficiaries) can sue to enforce contracts. *See Starkey v. Mill*, 82 Eng. Rep. 723 (K.B. 1651); *Dutton v. Poole*, 83 Eng. Rep. 523 (K.B. 1677). Following that English precedent, courts in this country long have held that, "where one person makes a promise to another for the benefit of a third person, that third person may maintain an action on such promise." *Schemerhorn v. Vanderheyden*, 1 Johns. 139, 140 (N.Y. Sup. Ct. 1806) ("The same principle has, since [*Dutton*], been repeatedly sanctioned by the decisions of the *English* courts."); *see also, e.g.*, *German Alliance Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220, 230 (1912) (third party may enforce contract "intended for his direct benefit"); *Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303, 307 (1927) (same); *United States ex rel. Johnson v. Morley Constr. Co.*, 98 F.2d 781, 788-89 (2d Cir. 1938) (L. Hand, J.); *Crumady v. The Joachim Hendrik Fisser*, 358 U.S. 423, 428 (1959); *Arthur Andersen LLP v. Carlisle*, 129 S. Ct. 1896, 1902 n.6 (2009) (noting "contract law's longstanding endorsement of third-party enforcement"); Melvin Aron Eisenberg, *Third-Party Beneficiaries*, 92 Colum. L. Rev. 1358, 1360-89 (1992) (discussing history).

Under modern doctrine, a third party is an intended (as opposed to incidental) beneficiary when "recognition of a right to performance in the beneficiary is appropriate to effectuate the intention of the parties and . . . the circumstances indicate that the promisee intends to give the beneficiary the benefit of the promised performance." Restatement § 302(1)(b).

Accordingly, an "intended beneficiary may enforce the duty." *Id.* § 304.

The same rule applies to a government contract, "except to the extent that application would contravene the policy of the law authorizing the contract or prescribing remedies for its breach." *Id.* § 313(1); *see Mobil Oil*, 530 U.S. at 608 (applying Restatement to interpret federal government contract); *Miree v. DeKalb County*, 433 U.S. 25, 32 (1977) (acknowledging state-law third-party beneficiary claim on contract between Federal Aviation Administration and municipality); *Audio Odyssey, Ltd. v. United States*, 255 F.3d 512, 520-22 (8th Cir. 2001) (holding small-business borrower was intended third-party beneficiary of loan guarantee agreement between lender and Small Business Administration); *Holbrook v. Pitt*, 643 F.2d 1261, 1269-73 (7th Cir. 1981) (holding tenants were intended third-party beneficiaries of contracts between developers of low-income housing and Department of Housing and Urban Development).

Where a third party does not seek consequential damages but only general damages — as here, where respondent seeks only reimbursement for manufacturers' overcharges in breach of their contractual promises — courts generally uphold the third party's rights as an intended beneficiary entitled to sue. *See* 3 E. Allan Farnsworth, *Contracts* 688-89 (3d ed. 1999) (where "consequential damages are not involved, so that the promisor's risk is more limited, . . . courts have permitted enforcement [of government contracts] by third persons"); Restatement § 313 cmt. a.

**2.** As both courts found below, 340B entities are intended third-party beneficiaries of the provision in the Agreement mandating that manufacturers

charge 340B entities prices that do not exceed the same best prices that States receive through Medicaid rebates. *See supra* pp. 15-17. Petitioners no longer dispute that 340B entities are, as a matter of contract law, intended third-party beneficiaries of the Agreement, having waived that issue in their certiorari petition, *see* Br. in Opp. 31-33, and failing to argue it in their merits brief.

The Agreement requires manufacturers "to charge covered entities a price . . . that does not exceed" the ceiling price. Agreement § II(a). Because 340B entities are specifically named in the Agreement, and because manufacturers have contracted to charge them no more than the ceiling price, 340B entities are intended third-party beneficiaries entitled to enforce that promise. *See, e.g.*, Restatement §§ 302(1)(b), 304.

Moreover, 340B entities' status as intended third-party beneficiaries can be traced directly to judgments of Congress, which expressly required an "agreement" containing a provision limiting "the amount required to be paid . . . by a covered entity" to an amount that "does not exceed" the ceiling price. § 256b(a)(1). Congress also described the Agreement as one "between the [340B] entity and the manufacturer." § 256b(a)(5)(D).

The legislative history accords with the unambiguous statutory text. Congress enacted § 256b, with its contract mechanism, specifically "to enable . . . certain Federally-funded clinics [*i.e.*, 340B entities] to obtain lower prices on the drugs that they provide to their patients" and "to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." 1992 House Report at 7,

12. As the court of appeals concluded, one is "unable to discern any substantial purpose of the [Agreement] *other* than to grant eligible covered entities a discount on covered drugs." App. 43a.

As the Ninth Circuit further determined, "the right to sue inheres in one's status as an intended beneficiary," because the right to sue is precisely what distinguishes intended from incidental beneficiaries. App. 39a (citing, *inter alia*, Restatement § 304 ("the intended beneficiary may enforce the duty")). There is no need to seek (as the district court mistakenly thought) additional indications that intended beneficiaries may enforce the ceiling price. *See Montana v. United States*, 124 F.3d 1269, 1273 (Fed. Cir. 1997) (rejecting such a requirement).

**3.** Finally, until recently, § 256b contained no statutory administrative remedy that arguably could displace the standard common-law breach-of-contract remedy available to intended third-party beneficiaries. As this Court has stressed specifically in the context of federal common-law remedies, when Congress seeks "to abrogate a common-law [remedial] principle, the statute ***must speak directly*** to the question addressed by the common law." *United States v. Texas*, 507 U.S. 529, 534 (1993) (emphasis added; internal quotations omitted) (Debt Collection Act of 1982 did not abrogate United States' federal common-law right to collect pre-judgment interest on debts owed to it by States); *see also Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605, 2619 (2008) (Clean Water Act did not displace federal common law of punitive damages, citing *Texas*); *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991) ("[W]here a common-law principle is well established, . . . the courts may take it as given that Congress has legis-

lated with an expectation that the principle will apply except 'when a statutory purpose to the contrary is evident.'") (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783 (1952)); *cf.* Restatement § 313. Applying this principle, the Court recently held that, because Congress did not "purport[] to alter background principles of state contract law" in the Federal Arbitration Act, a "third-party beneficiary" to a contract could seek a stay to enforce a contract's arbitration provision. *Arthur Andersen*, 129 S. Ct. at 1902 (internal quotations omitted).

In claiming that Congress meant for 340B entities to have no contract enforcement rights, the United States (at 30-31) relies on provisions in the Medicaid statute (enacted two years before § 256b) that provide for civil monetary penalties and termination from Medicaid as potential sanctions for manufacturers' failure to report accurate prices. *See also* Pet. Br. 38. Neither provision displaces a breach-of-contract remedy for 340B entities to enforce the Agreement. Indeed, the United States draws the wrong conclusion from Congress's silence on 340B entities' contract-enforcement rights. The applicable principle is that Congress must speak clearly when it intends to displace common-law remedies. *See Beck*, 529 U.S. at 501 ("'[A]bsence of contrary direction may be taken as satisfaction with widely accepted [common-law] definitions, not as a departure from them.'") (quoting *Morissette*, 342 U.S. at 263).

Furthermore, the only administrative procedure for 340B entities to recover overcharges was purely elective. *See* 2005 Deficiencies Report at 16-17. HHS made clear that "[c]overed entities or manufacturers are not required" to use the informal process. 61 Fed. Reg. at 65,411. HHS also acknowledged that

such "parties" may instead "resort[] to other remedies which may be available under applicable principles of law," which is what respondent has done here. *Id.* at 65,411-12.[44]

## II. NEITHER PETITIONERS NOR THE UNITED STATES PROVIDE GROUNDS FOR IGNORING CONGRESS'S DECISION TO IMPLEMENT § 256B THROUGH ENFORCEABLE FEDERAL CONTRACTS

### A. This Court's Private-Right-Of-Action Case Law Is Inapposite

1. As this Court has recognized, cases in which a party seeks to enforce provisions in a contract that Congress mandated to implement a statutory scheme "do[] not fit comfortably in th[e] mold" of "private right of action case[s]." *Jackson Transit*, 457 U.S. at 20. A plaintiff may "state[] a federal claim when he sue[s] to vindicate contractual rights set forth by federal statutes, ***despite*** the fact that the relevant statutes lacked express provisions creating federal causes of action." *Id.* at 22 (emphasis added).

Nonetheless, petitioners and their *amici* — except, notably, the United States — attempt to force this case into the implied private right of action mold. Petitioners and these *amici* offer no explanation for Congress's decision to implement § 256b through what petitioners recognize (at 42) are "federal contract[s]." Congress instead could have required manufacturers, as a condition on Medicaid coverage for their drugs, to charge 340B entities no more than

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[44] The United States (at 31-32) contends that HHS did not there suggest that 340B entities (as opposed to manufacturers) were among the "parties" with "other remedies," but that is the only reasonable reading of "parties" in context.

the ceiling price, with the Secretary directed to promulgate regulations to implement that requirement. Under such a hypothetical statute, 340B entities would need a private right of action to enforce the statutory and regulatory obligations Congress and HHS imposed.

On petitioners' view, that hypothetical statute is no different from the one Congress actually enacted, which deprives of all meaning Congress's choice to require contracts and violates "one of the most basic interpretive canons, that a statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." *Corley v. United States*, 129 S. Ct. 1558, 1566 (2009) (internal quotations and alteration omitted); *see also Bennett v. Spear*, 520 U.S. 154, 173 (1997).[45]

Petitioners' invocation of the Court's implied-right-of-action cases is thus entirely misplaced. That is true in particular of *Alexander v. Sandoval*, 532 U.S. 275 (2001), which considered whether "language in a regulation can conjure up a private cause of action that has not been authorized by Congress." *Id.* at 291; *see id.* at 292 (noting that the regulations at issue went "beyond the statutory prescription of [42 U.S.C. § 2000d]"). Here, in contrast, *Congress* mandated the creation of enforceable contracts that would include a provision providing a benefit directly to 340B entities.

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[45] Petitioners' reliance (at 20-21) on cases arising under the Spending Clause similarly ignores Congress's choice to implement section 340B through actual contracts, rather than a Spending Clause mandate that is simply "in the nature of a contract." *Barnes v. Gorman*, 536 U.S. 181, 186 (2002) (internal quotations and emphasis omitted).

Equally flawed is petitioners' passing attempt (at 44) to distinguish *Jackson Transit* and cases in which this Court has recognized the existence of a federal cause of action to enforce federal contracts as raising only "a choice of law question." Petitioners ignore the Court's crucial antecedent recognition that Congress necessarily intends for contracts to be *enforceable*, regardless of whether a breach-of-contract claim is a federal- or state-law cause of action. *See Jackson Transit*, 457 U.S. at 29 n.13 (explaining that the "union, *of course*, can pursue a contract action," albeit there "in state court") (emphasis added).

Petitioners also erroneously claim (at 28-32) that a right to sue to enforce the ceiling price provision in the Agreement is no different from a private right of action to enforce § 256b. If 340B entities had a private right of action, they could enforce not only the terms of the Agreement, but also manufacturers' obligation to sign an Agreement in order to maintain coverage for their drugs under Medicaid. *See* §§ 256b(a), 1396r-8(a)(1), (5)(A). Lacking that private right of action, 340B entities cannot compel a manufacturer to sign an Agreement or recover discounts from a manufacturer that was required, but refused, to sign an Agreement. That difference is significant. When respondent filed suit, a number of manufacturers benefiting from Medicaid coverage for their drugs still had not complied with their statutory duty to execute an Agreement.[46]

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[46] *See 2006 Oversight Hearing* at 46 (prepared statement of William H. von Oehsen, III, General Counsel, Public Hospital Pharmacy Coalition) ("[T]here are a number of manufacturers that have avoided or delayed entering into [a] 340B [Agreement] notwithstanding the continued coverage of their products by Medicaid.").

2. Petitioners claim (at 26-28) that two cases support precluding 340B entities from bringing a breach-of-contract claim to enforce the Agreement. Neither supports them.

*Universities Research Association, Inc. v. Coutu*, 450 U.S. 754 (1981), was *not* a breach-of-contract case. Instead, the plaintiff claimed a violation of the Davis-Bacon Act: namely, that the contract under which he was paid should have contained provisions requiring that he be paid the prevailing wage. Because the contract "does not contain a prevailing wage stipulation," the only question before the Court was whether the plaintiff had an implied private right of action under the Davis-Bacon Act. *Id.* at 756. The Court found that he did not. *See id.* at 771-784.

The Court, however, left open questions about the enforcement of a contract containing Davis-Bacon provisions and expressly noted the petitioners' concession at oral argument that an employee may have a state-law claim to enforce such a contract as an intended third-party beneficiary. *See id.* at 769 n.19. The United States, in its *amicus* brief in *Coutu*, had gone further and argued that "[t]here is no need for the Court to decide in this case whether such a private right of action may be implied in favor of an employee under a contract that *contains* Davis-Bacon stipulations," because an employee claiming a breach of that contract "should be able to recover in a suit on the contract as a third-party beneficiary." U.S. Amicus Br. at 17 n.14, *Universities Research Ass'n*,

*Inc. v. Coutu*, No. 78-1945 (U.S. filed June 1980); *see id.* at 22 (same).[47]

Equally inapposite is *United States v. Erika, Inc.*, 456 U.S. 201 (1982). There, the Court found that Congress had precluded judicial review of Medicare Part B payment decisions. *See id.* at 206. The Court rejected the respondent's claim that it could sue "as a third-party beneficiary to [the insurer's] contract with the United States," explaining that "any such contract[] . . . necessarily would include the statutory preclusion of [judicial] review." *Id.* at 211 n.14.[48] Neither § 256b nor the Agreement contains any comparable provision that could preclude 340B entities from enforcing their rights as intended third-party beneficiaries to recover drug manufacturer overcharges.

**3.** Congress's decision to implement § 256b through federal contracts, against well-settled background principles that provide a cause of action for intended third-party beneficiaries, provides all the evidence of congressional intent necessary and must be respected. The Ninth Circuit's holding that 340B entities are intended third-party beneficiaries of the Agreement thus reflects neither "judicial creativity" nor "turn[ing] back the clock" on this Court's private-

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[47] Subsequently, some courts have found no right to enforce Davis-Bacon Act contracts as third-party beneficiaries on the ground that a binding administrative dispute resolution scheme — which is absent here — precludes such claims. *See, e.g., Grochowski v. Phoenix Constr.*, 318 F.3d 80, 85-86 (2d Cir. 2003) (cited at Pet. Br. 29).

[48] *See also Hodges v. Atchison, T. & S.F. Ry. Co.*, 728 F.2d 414, 416 (10th Cir. 1984) (finding third-party beneficiary claim precluded by "the comprehensive remedial scheme provided in the [Rehabilitation Act of 1973]").

right-of-action precedents (PhRMA Br. 9, 11), but rather enforcement of contracts *expressly required by Congress*, under long-settled principles in this Court and under the common law of contracts.

Certainly Congress may, by positive statutory enactment, establish administrative remedies that displace federal common-law remedies. *See, e.g., Firestone Tire & Rubber Co. v. Bruch*, 489 U.S. 101, 108 (1989). Unlike petitioners and their other *amici*, the United States argues (at 12-14) that the PPACA contains a new directive for HRSA to create an administrative process to resolve claims of overcharges, which the United States contends will preclude future breach-of-contract suits by 340B entities. Whether that process, once implemented,[49] will preclude future breach-of-contract claims is not presented here, as respondent's claims well precede the PPACA's enactment. Indeed, the United States concedes (at 12, 14) that this process "will not apply to the claims at issue in this case," as the statute applies only "to drugs purchased on or after January 1, 2010."[50]

### B. The United States' Novel Assertions Are Both Unsupported And Outside The Question Presented

The United States is unwilling to defend petitioners' reliance on the Court's implied-right-of-action case law. Instead, the United States advances erro-

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[49] HHS failed to meet Congress's deadline to promulgate regulations by September 19, 2010. *See supra* note 16.

[50] If the United States is correct that the remedy HHS creates for sales from January 1, 2010, forward through its new statutory authority is exclusive, it severely limits the importance of the Question Presented and arguably warrants dismissal of the certiorari petition as improvidently granted.

neous arguments not fairly included in the Question Presented or advocated by petitioners. *See Yee v. City of Escondido*, 503 U.S. 519, 535 (1992) ("[W]e ordinarily do not consider questions outside those presented in the petition for certiorari."); *Kamen v. Kemper Fin. Servs., Inc.*, 500 U.S. 90, 97 n.4 (1991) (declining to address issue raised solely by Solicitor General "because we do not ordinarily address issues raised only by *amici*"); Sup. Ct. R. 14.1(a).

*1. The United States' artificial distinction between "regulatory" contracts and "ordinary" contracts fails*

***a.*** Section 256b(a)(1) requires that "[t]he Secretary shall enter into an agreement with each manufacturer of covered outpatient drugs" to charge no more than the ceiling price. The Secretary implemented that directive by creating the Agreement. Petitioners, all of which signed an Agreement, recognize that the Agreement "is a federal contract," Br. 42; *see id.* at i (Agreement is "the contract"), as does the drug manufacturers' association, *see* PhRMA Br. 2, 9 ("contract"). The parties also agreed before the Ninth Circuit that the Agreement is a contract, and the United States nowhere disputed that fact, instead describing the Agreement as a "government contract" or "340B contract," U.S. C.A. Amicus Br. 12, 18, 26-27.

Now, however, the United States contends (at 15) that the Agreement is not any kind of a contract at all, but is, in effect, no different from an agency regulation because it "does not give rise to any enforceable contractual rights in manufacturers or in covered entities as third-party beneficiaries." That novel effort is an implicit concession that, *if* the Agreement is a federal contract (and if 340B entities are intended

third-party beneficiaries, another question that only the United States disputes), 340B entities have a federal cause of action.

*b.* The United States' attempt to deny that the Agreement is a contract fails. As the United States acknowledges (at 15), § 256b "is structured as an opt-in program in which drug manufacturers may voluntarily choose to participate." Although manufacturers have an obligation to enter an Agreement if they sell their drugs as part of the Medicaid program, the obligation to charge the ceiling price attaches only when the manufacturer signs the Agreement and not before. That feature further evidences that the Agreement is a contract. *See United States v. Bloom*, 112 F.3d 200, 204 (5th Cir. 1997) ("The statute [permitting academic scholarship awards] . . . does not of its own force subject the parties to [the statutory] conditions . . . . Not until the agreement is signed do the parties assume any responsibilities.").

The United States' position also conflicts with the origin of the statutory scheme. When Congress enacted the Medicaid Rebate Program, it allowed pre-existing contracts between manufacturers and state Medicaid programs to substitute for the statutory agreements so long as they provided equivalent benefits, evidencing Congress's understanding that the new rebate agreements were to be enforceable contracts no less than the existing ones. *See* § 1396r-8(a)(4); *supra* note 8. Two years later, Congress extended that same contracting regime to the 340B program.

*c.* The United States nonetheless claims (at 15) that the Agreement is "statutory and regulatory — not contractual — in nature" and thus unenforceable by "manufacturers or . . . covered entities." In

*Winstar*, however, a four-Justice plurality squarely rejected a similar argument, ruling that contracts applying regulatory policy are nevertheless enforceable. "[A]llowing the Government to avoid contractual liability merely by passing any 'regulatory statute' would flout the general principle that, '[w]hen the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals.'" 518 U.S. at 895 (plurality) (quoting *Lynch v. United States*, 292 U.S. 571, 579 (1934)) (finding that contracts between bank regulators and banks acquiring distressed thrifts were breached when Congress by statute changed the capital requirements on which the agreements were based, making the United States liable in damages) (second alteration in original). The plurality further noted that an exception for government "contracts that are 'regulatory' in nature ... would raise enormous analytical difficulties" because "the Government may wish to further its regulatory goals through contract." *Id.* at 886.[51]

The cases the United States cites (at 14-21) suggest only that some contract-law principles apply differently to contracts that implement federal statutes. But none suggests that breach-of-contract remedies do not exist for such contracts. Thus, in *Bennett v. Kentucky Department of Education*, 470 U.S. 656 (1985), this Court *enforced* a federal grant agreement, declining only to rule "that ambiguities ... should invariably be resolved against the Federal Government as the drafter of the grant agreement." *Id.* at 669. In *Bowen v. Public Agencies Opposed to*

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[51] The three Justices concurring in the judgment raised no objection to that analysis.

*Social Security Entrapment*, 477 U.S. 41 (1986), the Court held that a statutory agreement between federal and state governments necessarily incorporated Congress's statutory reservation of rights to amend the Social Security Act and thus did not create vested Fifth Amendment property rights. *Id.* at 54. In other cases, this Court found merely that there was no government contract — not that any such contract was unenforceable. *See Flemming v. Nestor*, 363 U.S. 603, 610 (1960) (employees have only a "noncontractual interest" in Social Security benefits); *United States R.R. Retirement Bd. v. Fritz*, 449 U.S. 166, 174 (1980) ("[R]ailroad benefits, like social security benefits, are not contractual and may be altered or even eliminated at any time."); *National R.R. Passenger Corp. v. Atchison, T. & S.F. Ry. Co.*, 470 U.S. 451, 465 (1985) (railroads' contracts with Amtrak, a private corporation, were not with the United States).[52]

Among lower-court cases, the United States (at 17, 18, 20) relies primarily on *Rendleman v. Bowen*, 860 F.2d 1537 (9th Cir. 1988), which held only that, in interpreting statutory contracts between the Government and scholarship recipients, "[s]tatutory intent ... is more relevant to the interpretation of these conditions." *Id.* at 1541 (enforcing contract).[53] And the same court subsequently "reject[ed] the government's understanding of the [statutory] scholar-

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[52] *See also Hollander v. Brezenoff*, 787 F.2d 834, 838 (2d Cir. 1986) ("appellant does not claim that any specific obligation undertaken in [government] agreements was breached") (cited at U.S. Br. 20).

[53] *See also American Hosp. Ass'n v. Schweiker*, 721 F.2d 170, 183 (7th Cir. 1983) (contractual "scope and interpretation" was a question "more of statutory construction than of contract law") (cited at U.S. Br. 17, 20).

ship agreement [at issue in *Rendleman*] as noncontractual," because "Congress described the agreement between the scholarship recipient and government as a 'contract'" in the relevant statute. *United States v. Westerband-Garcia*, 35 F.3d 418, 420 (9th Cir. 1994) (applying federal statute of limitations for contracts). Moreover, contrary to the United States' suggestion (at 18), "[t]he fact that the parties do not bargain for the terms of the agreement, but must take the terms as set forth in [the statute], does not mean that the agreement is not a contract." 35 F.3d at 421. Under the United States' rationale, no consumer's assent to a corporation-drafted form agreement would ever be deemed a "contract." *But see* Restatement § 211 (assent to "[s]tandardized [a]greement[]" creates legally enforceable contract).

In all events, to conclude that statutory provisions incorporated in government contracts bear on "the parties' likely intent . . . *is to apply, not to disregard*, the ordinary rule of contract law." *Winstar*, 518 U.S. at 913 (Breyer, J., concurring) (emphasis added). Moreover, Congress's ability to alter the Agreement's terms legislatively is not germane to whether the existing terms are contractually enforceable. *See* U.S. Br. 19-21. It shows only that manufacturers agreed in the Agreement that referenced statutory definitions would apply as Congress might amend them from time to time. *See, e.g.*, Agreement § 1(b) ("'*Best Price*' has the meaning given it in [§ 1396(c)(1)(C)]").

***d.*** Finally, the United States attempts to draw support for its claim that the Agreement is not enforceable through a breach-of-contract suit by pointing to Congress's recent enactment of the PPACA, which it suggests "demonstrates that Congress regards the 340B Program as essentially statutory and

regulatory — not contractual — in nature." U.S. Br. 14, *see id.* at 33. This Court often has held that later enactments are "'beside the point'" in construing prior ones. *Gutierrez v. Ada*, 528 U.S. 250, 258 (2000) (quoting *Almendarez-Torres v. United States*, 523 U.S. 224, 237 (1998)). The new provisions designed to ensure 340B program integrity are, however, congressional confirmation that HRSA was not fulfilling the statute's goal of ensuring that 340B entities get the best prices available in the marketplace. That later enactment thus may imply that Congress perceived existing contract actions to enforce manufacturers' obligations in the Agreement to be insufficient, but it says nothing about whether § 256b properly is construed to create contracts enforceable through third-party beneficiary claims. Instead, under this Court's decisions, Congress's use of contracts requires that they be treated as such when manufacturers breach the Agreement.

*2. 340B entities are intended third-party beneficiaries of the Agreement*

Despite petitioners' waiver of the claim, *see supra* p. 33, the United States disputes that 340B entities are intended third-party beneficiaries entitled to enforce manufacturers' promise to charge no more than the ceiling price. But in contending that the Secretary did not intend for the Agreement to create such third-party rights, the United States asks (at 25-27) the wrong question. It was Congress that required the Secretary to draft a contract that included a provision specifically intended to benefit 340B entities. The Secretary had no discretion to exclude that provision from the Agreement or to preclude any third-party beneficiary rights that flow from that provision. Moreover, the United States' claim conflicts

with Congress's description of the Agreement as one "between the [340B] entity and the manufacturer." § 256b(a)(5)(D).[54]

The United States, however, claims (at 26-27) that the Agreement provision permitting the Secretary or a manufacturer, but not a covered entity, to initiate the Agreement's voluntary dispute resolution process indicates that the Secretary did not intend to confer third-party beneficiary rights on covered entities. Again, the United States asks the wrong question, because *Congress's* intent controls here, as reflected in the provisions of the Agreement that Congress mandated, not the Secretary's subjective intent. In any case, there is no asymmetry in the elective dispute resolution process, because the Secretary has a separate elective procedure that covered entities can use. *See* U.S. Br. 26-27 (citing 61 Fed. Reg. at 65,412).

Nor is it significant that 340B entities typically buy their supplies from wholesalers and thus lack "privity" with the manufacturer. U.S. Br. 27-28. Congress expressly provided in the statute for such wholesale arrangements and, at the same time, required manufacturers to charge 340B "covered entit[ies]" an amount that "does not exceed" the ceiling price. § 256b(a)(1); *see* § 256b(a)(8) ("Secretary shall establish a prime vendor program" for "distribution of cov-

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[54] The United States similarly asks the wrong question in claiming (at 28-29) that the statutory confidentiality provision precluded the Secretary from deciding to confer intended third-party beneficiary status on 340B entities. In any event, as explained below, the United States' reliance on the confidentiality provision lacks merit. *See infra* pp. 52-53.

ered outpatient drugs").[55] Thus, the statutory text plainly expresses Congress's intent to benefit 340B entities, irrespective of privity with manufacturers.

## III. ACTIONS BY 340B ENTITIES TO REMEDY DRUG MANUFACTURER OVERCHARGES ARE CONSISTENT WITH FEDERAL ENFORCEMENT EFFORTS AND SOUND POLICY

### A. Congress Did Not Intend For Exclusive Federal Enforcement Of The Agreement's Ceiling-Price Provision

Enforcement of the Agreement by 340B entities complements, without interfering in, federal enforcement efforts.

**1.** Respondent seeks to enforce the ceiling-price provision of the Agreement; it does not seek to impose additional or different obligations on manufacturers. The United States previously recognized that principle in an *amicus* brief authorized by the Solicitor General in the context of a State's allegations that a manufacturer had concealed its actual best prices:

> [Where] a state sues a drug manufacturer that failed to calculate its best price obligations in accordance with the rebate agreement or CMS guidance — but does *not* seek to impose any additional or contrary obligations — the state is merely enforcing the existing rebate program responsibilities and does not inject any more var-

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[55] *See also* 2006 Overcharge Report at 2 ("If a manufacturer's drugs are available to entities through wholesalers, the 340B discount must be made available through that avenue.") (citing 59 Fed. Reg. 25,110, 25,113 (May 13, 1994) ("A covered entity is permitted to use a purchasing agent without forfeiting its right to the section 340B drug discounts.")).

> iation [in the national Medicaid regime] than if the Department of Justice brought suit.

U.S. *Mass.* Amicus Br. 17 (emphasis added); *see also* U.S. Br. 34 n.14 (citing same brief).

Relying on that *amicus* brief, the Massachusetts district court later held (in a separate case) that States can sue drug manufacturers to enforce the best-price and other requirements of the Medicaid rebate agreement as a "third-party intended beneficiary," despite the absence of a private right of action in that statute. *Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 329 (D. Mass. 2005) (citing U.S. *Mass.* Amicus Br. 17). The court found that allowing States to sue as intended third-party beneficiaries was "consistent with the statutory scheme, and not an end-run on it." *Id.* at 328.

**2.** The United States also has made clear that courts are well-suited to adjudicate claims, like respondent's here, that manufacturers improperly have excluded bundled discounts in calculating the best prices of their brand-name drugs. In the pending FCA case against Wyeth, the United States successfully defended against Wyeth's motion to dismiss — in which Wyeth raised arguments similar to those in petitioners' brief here[56] — by arguing that "[w]hether transactions under [Wyeth's contracts] constitute 'bundled sales' is ultimately a matter for judicial interpretation, and it is Wyeth's compliance with those requirements, as interpreted by the Court, that determines whether it submitted false Best Price reports." U.S. Opp. to Motion To Dismiss at 37, *United States ex rel. Kieff v. Wyeth*, Nos. 03-

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[56] *Compare* Wyeth Motion To Dismiss at 31-39, *United States ex rel. Kieff v. Wyeth*, Nos. 03-CV-12366-DPW & 06-CV-11724-DPW (D. Mass. filed Nov. 6, 2009), *with* Pet. Br. 33-37.

CV-12366-DPW & 06-CV-11724-DPW (D. Mass. filed Dec. 11, 2009) ("U.S. *Wyeth* MTD Opp."); *see id.* at 38 (explaining that Wyeth's reported best prices are "objectively false" if, "as the government contends," Wyeth improperly excluded bundled discounts from its best-price calculations).

Indeed, the United States rejected Wyeth's contention — which is identical to petitioners' assertion here (at 33-34) — that regulatory ambiguities render best-price calculations inherently too complex for such objective determinations. The United States argued that any complexity is "not an excuse for Wyeth to ignore the Rebate Agreement" and expressly endorsed the Ninth Circuit's ruling below in this case, which had "specifically rejected the argument by Wyeth (and other manufacturers) that the Rebate Agreement was in all cases too complex for a court to enforce without first referring the matter to the Secretary." U.S. *Wyeth* MTD Opp. 40 n.18; *see also Bates*, 544 U.S. at 452 ("While it is true that properly instructed juries might on occasion reach contrary conclusions on a similar issue of misbranding, there is no reason to think such occurrences would be frequent or that they would result in difficulties beyond those regularly experienced by manufacturers of other products that every day bear the risk of conflicting jury verdicts."). To the extent difficult issues arise, they can be dealt with through primary jurisdiction referrals. But many disputes will not implicate the agency's expertise, as the United States made clear below, because "it could turn out that any overcharging resulted from . . . obvious and intentional fraud that does not implicate the agency's interpretative expertise." U.S. C.A. Amicus Br. 25.

Court decisions to make such primary jurisdiction referrals on a "case-by-case" basis (U.S. Br. 35 n.15) are perfectly consistent with the United States' position in the Ninth Circuit, urging that a decision on a primary jurisdiction referral await further factual development. *See* U.S. C.A. Amicus Br. 22. The United States' claim (at 35 n.15) that such referrals "could interfere with HHS's enforcement priorities" is overstated, because a primary jurisdiction referral is equivalent to a request for a declaratory ruling, which private parties are permitted to file without regard to the agency's "enforcement priorities."

A court's capability to determine whether manufacturers violated their duties under the Agreement is no different whether a case begins with a private whistleblower complaint under the FCA, a State's complaint under state law or for breach of the Medicaid rebate agreement, or a 340B entity's breach-of-contract complaint. The United States is mistaken (at 34 n.14) that suits by 340B entities are "quite different from suits by States" because "the United States would play a cooperative role" and thereby prevent "inconsistent judgments uninformed by HHS's expertise." Nothing *requires* the United States to join in a State's lawsuit or a private FCA case. *See Vermont Agency of Natural Res. v. United States ex rel. Stevens*, 529 U.S. 765, 770 (2000) (relator may pursue FCA claims alone if United States declines to do so). And nothing *precludes* the United States from intervening or participating as an *amicus* in a case brought by a 340B entity.

Thus, as this Court has found is true in other contexts, "[p]rivate remedies that enforce federal [statutory] requirements would seem to aid, rather than hinder, the functioning of [the statute]." *Bates*,

544 U.S. at 451; *see also Wyeth v. Levine*, 129 S. Ct. 1187, 1202 (2009) (rejecting federal preemption of state-law failure-to-warn claims where "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs") (footnote omitted); *id.* at 1203 n.12 (private suits "'can serve as a catalyst'" to identifying unlawful acts) (quoting *Bates*, 544 U.S. at 451).

Petitioners and the United States, however, assert that the confidentiality provision in the Medicaid rebate statute (§ 1396r-8(b)) precludes 340B entities from obtaining the discovery necessary to identify a manufacturer's failure to calculate best prices and AMPs in accordance with the terms of the Agreement. *See* Pet. Br. 40; U.S. Br. 28-29. However, the data that respondent needs to show a violation of the ceiling-price provision are (a) the prices it paid, which respondent knows, and (b) the manufacturers' actual best price, which is determined using materials never provided to the federal government. The confidentiality provision covers neither set of data.

Moreover, the confidentiality provision has no application to court litigation. As the United States has explained, § 1396r-8(b) "does not preclude" a plaintiff from obtaining data necessary to identify a failure to calculate AMP or best price in accordance with the terms of the Agreement "from other sources (such as Defendants)." U.S. *Mass.* Amicus Br. 15; *see also* App. 20a-21a (rejecting petitioners' claim that confidentiality provision precludes production pursuant to "discovery order" and noting that "courts routinely enter protective orders to prevent the undue disclosure of commercially sensitive information").

3. The United States has concluded elsewhere that "it is unreasonable to infer that the Secretary should bear the sole responsibility for monitoring best price fraud." U.S. *Mass.* Amicus Br. 14. As the United States there explained, the Medicaid "rebate statute [§ 1396r-8] does not contain any provision . . . that would suggest a Congressional desire for exclusive federal enforcement." *Id.* at 13-14. The United States further stressed that the Medicaid "drug rebate scheme . . . is not specifically designed for identifying fraud." *Id.* at 14. Thus, "neither the rebate statute nor rebate agreement provides for the periodic or systematic review [by CMS] of manufacturer best price calculations or methodologies." *Id.* Moreover, the "rebate program does not require manufacturers to submit invoices to support their best price calculations or to regularly explain their methodologies for calculating AMP or best price." *Id.*; *see In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 199 (D. Mass. 2004) (noting that "the Secretary does not make an independent determination with respect to Best Price"). The United States' *amicus* brief below likewise acknowledged that "[m]anufacturers normally do not report the data or reasoning underlying their AMP and Best Price calculations." U.S. C.A. Amicus Br. 4.

Accordingly, the United States' description (at 30) of the Medicaid statute as containing a "comprehensive remedial scheme that enables HHS to ensure that manufacturers accurately calculate and report AMP and Best Price," and its related claim (at 32-33) that "Congress centralized enforcement in the [federal] government," are squarely at odds with its previous — and correct — positions on those issues in the Massachusetts case. *See also* Pet. Br. 32-33

(similarly asserting that Congress enacted "comprehensive" administrative enforcement regime). The Solicitor General, which approved the United States' *amicus* submission in the Massachusetts case, offers no reason here based in any change in law for the United States' change of position.

The United States' earlier court submission that the Secretary is not the exclusive enforcer of manufacturers' obligations with respect to AMPs and best prices applies with even greater force in the context of § 256b. Nothing in the Agreement (or § 256b) requires manufacturers to submit to HRSA the documents and data necessary to verify the best and average manufacturer prices reported to CMS, which HRSA uses to calculate the ceiling price under the Agreement. Nor does (pre-PPACA) § 256b contain any provision suggesting exclusive enforcement by the Secretary. Indeed, only in 2010 — 18 years into the program — did HRSA first receive statutory authority "to verify the accuracy of ceiling prices." § 256b(d)(1)(B)(i).

### B. Actions By 340B Entities To Enforce The Agreement Are Necessary In Light Of The Near-Complete Absence Of Federal Enforcement To Remedy Manufacturer Overcharges

Although petitioners and the United States repeatedly identify actions that HHS "may" take to remedy manufacturer overcharges, Pet. Br. 38-39; U.S. Br. 4-5, they are notably silent about actions HHS *has* taken, despite a steady stream of government reports and whistleblower suits revealing extensive over-

charging by manufacturers.[57] In fact, HHS enforcement has been almost non-existent and has been patently insufficient to protect 340B entities.

Although manufacturers are required to report their best prices and AMPs to the Secretary (via CMS), *see* § 1396r-8(b)(3)(A), they are not required to provide documents and analyses supporting those reported prices — much less documents that would reveal a manufacturer's improper exclusion from its reported best prices of bundled discounts, kickbacks, lick-and-stick sales, or other schemes. *See* U.S. *Mass.* Amicus Br. 14. As GAO explained, CMS "does not generally review the methods and underlying assumptions that manufacturers use to determine best price and AMP" and "does not verify that such documentation is kept and rarely requests it." 2005 Inadequate Oversight Report at 11. Even where "OIG found problems with manufacturers' price determination methods and reported prices . . . , CMS has *not* followed up with manufacturers to make sure that the identified problems with prices and price determination methods have been resolved." *Id.* at 10 (emphasis added).

Because CMS does not verify manufacturers' reported best prices and AMPs, the 340B ceiling prices calculated using those reported prices likewise are not verified. HRSA also "does not conduct audits or spot checks" of the prices 340B entities actually pay

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[57] Although the Medicaid statute provides authority for the Secretary to terminate either an Agreement or a Medicaid rebate agreement, *see* § 1396r-8(b)(4)(B)(v), OIG has concluded that this is an "extremely severe sanction" that has the counterproductive effect of limiting "access to medications for the millions of Medicaid and 340B beneficiaries." 2005 Deficiencies Report at 16.

and so is "unable to detect whether . . . entities are paying" more than the ceiling prices calculated using the unverified figures reported to CMS. 2005 Deficiencies Report at 15, 16. Neither agency has the staff or budget to engage in meaningful reviews of drug manufacturers' reported AMPs and best prices for the more than 35,000 drugs (*see* Pet. Br. 34) that Medicaid and 340B entities purchase. *See* 2010 Noncompliance Report at 14.[58] In sum, the agency undertakes virtually no investigation and enforcement of the veracity of the best-price and AMP figures manufacturers use to calculate the 340B ceiling prices (or, for that matter, of the figures used to calculate state Medicaid rebates).

The only enforcement alternative to intended third-party beneficiary suits for sales to 340B entities (prior to full implementation of the PPACA) is whistleblower suits under the FCA, on which the United States and petitioners' trade association — but not petitioners themselves — rely. *See* U.S. Br. 30-31; PhRMA Br. 14-15. But hoping that insider whistleblowers will come forward with evidence of best-price violations and be able to navigate the intricate jurisdictional requirements of a successful FCA suit is hardly a sensible primary enforcement

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[58] The United States' claim that "HRSA has implemented many improvements in response" to the highly critical OIG reports is wholly unsubstantiated. *See* U.S. Br. 32 n.13 (citing 2005 Deficiencies Report at 9-10, 12 (criticizing HHS's best-price and AMP "pricing data" and "general lack of detailed procedures for calculating the 340B ceiling price" as being "of little use to the agency's oversight of the 340B Program")). It is, moreover, contradicted by Congress's judgment in the PPACA that HHS — at long last — must "develop[] . . . a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers." § 256b(d)(1)(B)(i).

mechanism for such an important government program. Notably, the United States cites no authority suggesting that the FCA displaces longstanding and pre-existing common-law remedies for breach of contract. Moreover, FCA cases require a showing that the violation was made "knowingly" and allow for treble damages and fines in appropriate cases. 31 U.S.C. § 3729(a)(1), (2). Third-party breach-of-contract actions, in contrast, have no scienter requirement and seek only general damages (that is, a refund of the amounts overcharged), and thus focus more directly and comprehensively on the harm that 340B entities suffer when manufacturers breach the Agreement and charge more than the ceiling price for their drugs.

Petitioners assert (at 40-41) that 340B entities and States have differing interests in combating manufacturer misreporting of the AMP with respect to drugs where the best price does not determine the ceiling price.[59] Although it suggested similarly in the court below, the United States no longer advances that contention. In this Court, petitioners offer no claim that manipulating average prices is materially profitable to manufacturers or that the supposed conflict between States and 340B entities in this regard is anything other than hypothetical. In contrast, best-price manipulation can be highly lucrative for petitioner drug manufacturers; the whistleblower cases and government reports *all* concerned best-price manipulation. *See supra* pp. 8-11.

As petitioners acknowledge (at 41), the interests of 340B entities and States are perfectly aligned

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[59] For some brand-name drugs, the ceiling price is AMP minus 15.1%, and for non-brand-name drugs it is AMP minus 11%. *See supra* note 15.

with respect to eliminating manufacturers' best-price manipulation — the only realistic means by which manufacturers engage in overcharges. Such a parallel action by the entities that Congress specifically intended to benefit in § 256b and that bear the full brunt of manufacturers' overcharges complements any federal enforcement efforts. It also vindicates the congressional objective of ensuring that covered entities have access to the best pharmaceutical prices in stretching scarce governmental resources to provide medical services for the neediest persons.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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# REPLY BRIEF

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IN THE

# Supreme Court of the United States

ASTRA USA, INC., *et al.*,
*Petitioners*,

v.

COUNTY OF SANTA CLARA,
ON BEHALF OF ITSELF AND
ALL OTHERS SIMILARLY SITUATED,
*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

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| CMS, Medicaid Drug Rebate Program Release No. 47 (2000), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp | 21 |

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CMS, Medicaid Drug Rebate Program Release No. 68 (2005), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp ..... 21

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**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## REPLY BRIEF

Respondent seeks what the 340B Act indisputably fails to provide it: a cause of action. Whether this suit is framed as a breach of contract action under federal common law or an implied right of action under the statute, the substantive right respondent asserts and the private remedy it seeks are one and the same.

Abandoning the argument made below and the Ninth Circuit's rationale, respondent concedes that congressional intent—and not the parties' intent as interpreted under the common law—is the relevant touchstone for whether covered entities have a

private right to enforce a manufacturer's obligations under the 340B Act. Respondent also concedes that the Act does not confer an express or implied right of action under this Court's precedents including *Gonzaga University v. Doe*, 536 U.S. 273 (2002), and *Alexander v. Sandoval*, 532 U.S. 275 (2001). Resp. Br. 17 n.41, 36-38. Those concessions bring this case to an end. If Congress did not intend 340B entities to enforce a manufacturer's ceiling price obligations under the Act itself, then Congress did not intend to allow those entities to enforce those same obligations anyway under the rubric of federal common law.

The feature of an "agreement" between the Secretary of Health and Human Services ("the Secretary") and manufacturers, 42 U.S.C. § 256b(a)(1), does not authorize common law suits by 340B entities. That statutory "agreement" imposes ceiling price obligations on manufacturers that (1) run explicitly only to the Secretary as the other party to the agreement; (2) are based on information that is confidential and cannot be disclosed by the Secretary; and (3) are accompanied by specific rights that manufacturers have against covered entities but without any corresponding rights running in favor of covered entities. Congress moreover empowered the Secretary, who administers both the 340B program and the interrelated and much larger Medicaid Rebate program, to resolve the multitude of complexities and ambiguities in pricing methodology, to balance the potentially conflicting objectives between the two programs, and to audit and impose penalties to ensure compliance with both Acts.

Just like suits under an implied right of action, suits under the common law by more than 14,500 covered entities to challenge hundreds of thousands,

if not millions, of pricing transactions for all drugs covered by Medicaid would seriously disrupt that scheme. Such suits would also conflict with the flexibility that the Secretary has conferred on manufacturers to make reasonable assumptions in calculating Average Manufacturer Price ("AMP") and Best Price ("BP").

Allowing third parties to enforce the Act under federal common law would eviscerate the principles of *Gonzaga*, *Sandoval*, and decades of similar precedent and supplant them with a rule that would presumptively confer enforceable rights on all purported beneficiaries of federal public welfare programs administered through contracts. That regime would illegitimately expand the Article III power of the judiciary to invent through the back door what Congress declined to allow through the front door.

### A. Common Law Suits Would Circumvent The Absence Of A Private Right Of Action

1. Respondent argues that Congress mandated the Pharmaceutical Pricing Agreement ("PPA") against a background common law rule that permits certain third-party beneficiaries to sue to enforce an agreement. Resp. Br. 30-36. But if that rule governs, respondent loses. Respondent disavows the rule under common law, *id.* at 22, 47-48, presumably because it would require respondent to make the counter-factual showing that the Secretary and petitioners intended to confer enforceable rights on covered entities. *See* Restatement (Second) of Contracts § 302(1) (1981) ("[A] beneficiary of a promise is an intended beneficiary if recognition of a right . . . is appropriate to effectuate the *intention of the parties*.") (emphasis added); *id.* § 304 cmt. b ("[T]he parties to a contract have the power, *if they*

*so intend*, to create a right in a third person.") (emphasis added).

Respondent thus repeatedly asks this Court to ignore the Secretary's intent *not* to confer enforceable rights in the PPA. Resp. Br. 22, 47-48. Respondent contends that it could enforce the PPA under federal common law even if the PPA had *expressly* precluded suits by covered entities. *Id.* at 47. *But see* Restatement (Second) of Contracts § 302(1) (promisor and promisee may agree to preclude third party rights). Respondent recognizes that, because the manufacturers' obligation to charge prices no higher than the 340B ceiling price derives *in haec verba* from the 340B Act, respondent must show that *Congress* intended to create a cause of action in favor of 340B entities. Resp. Br. 22, 37, 47-48. But if congressional intent is the definitive guidepost, this Court should not accept anything less than that required by *Gonzaga* and similar cases.

In *Gonzaga*, this Court rejected a university student's attempts to enforce the private remedy expressly granted under 42 U.S.C. § 1983 against Gonzaga University for allegedly violating the Family Educational Rights and Privacy Act ("FERPA"), 20 U.S.C. § 1232g. This Court held that the student could not satisfy the requirements of a § 1983 claim because FERPA did not "unambiguously" and with "explicit rights-creating" language create a private remedy in favor of students. *Gonzaga*, 536 U.S. at 283, 284, 287. The fact that FERPA benefitted the student was insufficient. *Id.* at 282, 284-85. Other decisions similarly have made clear that "[t]he question is not simply who would benefit from the Act, but whether Congress intended to confer federal rights upon those beneficiaries." *California v.*

*Sierra Club*, 451 U.S. 287, 294 (1981); *accord Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754, 771-72 (1981).

Congress did not, under those standards, authorize 340B entities to enforce the Act's drug pricing provisions. Congress authorized the Secretary to enforce those provisions. The 340B Act confers only one private remedy: drug manufacturers have a right to damages for a 340B entity's violation of the Act. 42 U.S.C. § 256b(a)(5)(D). By contrast, Congress provided no private remedy in favor of 340B entities allegedly injured by a manufacturer's pricing calculations. Moreover, the Act gives manufacturers audit rights to ensure 340B entities' compliance with the Act. *Id.* § 256b(a)(5)(C). The Act gives no similar right to 340B entities to audit a manufacturer's pricing calculations. *Cf. Touche Ross & Co. v. Redington*, 442 U.S. 560, 572 (1979) ("[W]hen Congress wished to provide a private damages remedy, it knew how to do so and did so expressly.").

The Act in fact contemplates that 340B entities are barred from second-guessing a manufacturer's AMP and BP calculations. Drug pricing information is "confidential," and the Secretary may not disclose underlying pricing data. 42 U.S.C. § 1396r-8(b)(3)(D). Yet this suit seeks an astonishingly massive and unwieldy audit of petitioners' AMP and BP calculations that comprise over $100 billion annually in drug sales. Pet. Br. 39-40; Resp. Br. 14 n.39. That scheme conflicts with what Congress, the Secretary, and drug manufacturers intended when the parties entered into the PPA.

The Court's analysis in *United States v. Erika, Inc.*, 456 U.S. 201 (1982), similarly precludes respondent from evading the absence of a right of action under the 340B Act by framing the same claim as a breach of contract. In *Erika*, Congress implemented the Medicare Act through contracts between the government and insurance carriers. The Court rejected the notion that a purported beneficiary under the Act could bring a third-party breach of contract claim to assert a right he could not bring under the Act itself. *Id.* at 211 & n.14.

Respondent dismisses *Erika* on the ground that "[n]either § 256b nor the Agreement contains any comparable provision that could preclude 340B entities from enforcing their rights as intended third-party beneficiaries." Resp. Br. 40. But the Act in *Erika* contained no provision precluding the purported beneficiary from suing. The Court nonetheless held that the statute's implicit preclusion of such a right is read into the contract. *Erika*, 456 U.S. at 211 n.14. By parity of reasoning, the preclusion of judicially enforceable rights under the 340B Act is a necessary component of the PPA.

Respondent also argues that its third-party beneficiary breach of contract suit does not circumvent the absence of an implied right of action because the latter might give covered entities the right to sue a manufacturer for refusing to sign a PPA when the manufacturer's drugs are covered by Medicaid. Resp. Br. 38. Even accepting that hypothesis, respondent's breach of contract suit to enforce the PPA's ceiling price obligations is substantively indistinguishable from an implied right of action to enforce those same obligations in the 340B Act. Both suits seek to enforce the same right and to obtain the same

remedy. Common law suits also would cause the same programmatic disruptions that Congress evidently sought to prevent when it concededly declined under the Act to provide for a private right to sue.

The government suggests that an agency through a contract may confer rights to enforce an *in haec verba* statutory requirement if Congress has delegated such rights-granting authority to the agency. Br. for the United States as Amicus Curiae ("U.S. Br.") 23-24. That position, however, is hard to reconcile with *Sandoval*, where the Court assumed that Congress had empowered the agency to promulgate regulations prohibiting funding recipients from engaging in practices with a discriminatory effect. 532 U.S. at 281-83, 286. The Court nonetheless held that even a validly promulgated regulation may not be the source of a cause of action; a private remedy must stem directly from Congress. *Id.* at 286-87. In any event, the government correctly explains that the Secretary did not intend to confer rights on 340B entities under the PPA. U.S. Br. 21-25.

2. Respondent argues that this Court's private right of action precedents are irrelevant because the 340B Act imposes the ceiling price obligations "through actual contracts, rather than a Spending Clause mandate that is simply 'in the nature of a contract.'" Resp. Br. 37 n.45 (quoting *Barnes v. Gorman*, 536 U.S. 181, 186 (2002)). But the contract mechanism employed in the 340B Act reflects Congress's choice to adopt an opt-in program, *i.e.*, the ceiling price obligations become effective only if manufacturers convey their written consent in the PPA. That arrangement does not reflect Congress's intent to confer a common law remedy on purported

beneficiaries any more than had Congress imposed the same funding obligation by regulation with the party's implicit consent. *Sandoval*, 532 U.S. at 288-91. Requiring manufacturers' explicit consent to the ceiling price obligations does not authorize courts to invent a cause of action under federal common law or to impose unanticipated liabilities on manufacturers.

The lack of a common law remedy for 340B entities does not render the PPA "meaningless." Resp. Br. 21; *accord id.* at 37. As stated, the Act's drug ceiling price provisions do not apply to drug manufacturers unless they enter into the PPA with the Secretary. 42 U.S.C. § 256b(a)(1); *see also* Health Res. & Servs. Admin., 340B Database: Manufacturer, http://opanet.hrsa.gov/opamod/Manufacturers.aspx (listing "inactive" manufacturers without an effective PPA). There is also a historic explanation for why Congress implemented the 340B Act through the PPA. The 340B Act borrowed the contract mechanism of the Medicaid Rebate Act, 42 U.S.C. §§ 256b(a)(1), 1396r-8(c), and the Medicaid Rebate Act in turn built upon pre-existing contracts between States and manufacturers providing for rebates, *id.* § 1396r-8(a)(4). *See also* Resp. Br. 43.

Respondent also obliquely relies on Section 256b(a)(5)(D), which refers to an "agreement *between the entity and the manufacturer* under this paragraph." Resp. Br. 7 (emphasis added); *accord id.* at 20, 33, 47-48. When read in context, Congress presumably meant to refer to the Secretary rather than a covered entity. *Cf. U.S. Nat'l Bank of Or. v. Indep. Ins. Agents of Am., Inc.*, 508 U.S. 439, 462 (1993). Section 256b(a)(5)(D) provides that 340B entities that divert covered drugs or receive 340B

discounts that improperly trigger Medicaid drug rebates are liable to the manufacturer for an amount equal to the total discount provided to the entity under the PPA for the diverted or Medicaid-billed product. *See also* Veterans Health Care Act of 1992: Summary of Provisions, 138 Cong. Rec. S17867 (Oct. 8, 1992) (Act would render covered entity "liable to the manufacturer in an amount equal to the reduction in the price of the drug provided under the rebate or discount agreement *with the Secretary of HHS*.") (emphasis added).

Covered entities are not parties to the PPA, and respondent has never suggested otherwise. Indeed, the premise of this suit is respondent's status as a *non*-party to the PPA. It strains credulity that an ambiguous reference contained in a formula for calculating the amount of reimbursement owed to manufacturers confers on 340B entities enforceable rights and remedies. Congress "does not, one might say, hide elephants in mouseholes." *Whitman v. Am. Trucking Ass'ns, Inc.*, 531 U.S. 457, 468 (2001).

3. In respondent's view, "Congress's decision to implement § 256b through federal contracts . . . provides all the evidence of congressional intent necessary" to presumptively establish a cause of action under federal common law. Resp. Br. 40. That premise is backwards. Statutes conferring federal common law authority on courts do not confer rights-granting authority to enforce a federal statute. *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 255 & n.5 (1993); *Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 643-46 (1981). Respondent's contrary view would transform the post-*Erie* precept that federal common law authority is exceedingly narrow and limited, Pet. Br. 42-44, into a rule that gives

federal courts expansive and free-wheeling power to trump the decision of Congress not to create a cause of action under a statute. *Cf. Sandoval*, 532 U.S. at 287 ("Having sworn off the habit of venturing beyond Congress's intent, we will not accept respondents' invitation to have one last drink.").

Respondent's proposed regime would seriously upset the expectations of government contractors and funding recipients that never anticipated that their contracts silently subjected them to class actions and potential sprawling lawsuits like this case. Pet. Br. 39-40; Br. of the Chamber of Commerce as Amicus Curiae 12-18. As discussed at the petition stage, this Court's modern implied right of action decisions have prompted enterprising lawyers to seek private enforcement of a statute by bringing a third-party breach of contract suit. Pet. 17-18. Respondent's proposal would pave the way for purported beneficiaries of numerous health care and other federal welfare statutes to bring common law suits seeking private enforcement of statutes that contain no implied right of action. Litigants already have begun to cite the decision below in seeking third-party beneficiary contract rights to enforce other government programs administered through contracts. *See, e.g.*, *Marques v. Wells Fargo Home Mortg., Inc.*, No. 09-cv-1985, 2010 WL 3212131 (S.D. Cal. Aug. 12, 2010) (Troubled Asset Relief Program ("TARP")).

### B. The Federal Nature Of The PPA Does Not Authorize A Common Law Cause Of Action

1. Respondent argues that *Jackson Transit Authority v. Local Division 1285*, 457 U.S. 15 (1982), and similar decisions establish that third-party beneficiaries of a federal contract may sue to enforce

the contract unless Congress affirmatively precludes such a suit. Resp. Br. 1, 19-20, 25-28, 36, 38. But none of those decisions so holds. Those cases resolve the question whether a breach of contract dispute between the parties to a contract should be resolved in a federal forum, rather than a state forum. *Jackson Transit* held that, although a federal statute contemplated future contracts between federal funding recipients and unions, Congress did not intend that disputes between the parties under such contracts be resolved in federal courts. 457 U.S. at 16, 29.

The other decisions relied upon by respondent, Resp. Br. 25-29, are to the same effect. *See Empire HealthChoice Assurance, Inc. v. McVeigh*, 547 U.S. 677, 693-99 (2006) (holding that contract-based claims between a federal employee insurance carrier and the insured arose under state law); *Norfolk & W. Ry. Co. v. Nemitz*, 404 U.S. 37, 44-45 (1991) (holding that suit between the parties to the federal contract arose under federal law). For similar reasons, respondent errs in faulting petitioners for not citing *International Association of Machinists v. Central Airlines, Inc.*, 372 U.S. 682 (1963), a case not cited by respondent until its merits brief. Resp. Br. 29. That decision merely holds that federal courts had subject matter jurisdiction to resolve a dispute between two parties to a contract mandated by federal law. *Central Airlines*, 372 U.S. at 691-96.

In *Miree v. DeKalb County*, 433 U.S. 25, 28 (1977), *see* Resp. Br. 32, the Court held that state law governed a third-party beneficiary claim to enforce a contract contemplated by an Act of Congress. *See also Boyle v. United Techs. Corp.*, 487 U.S. 500, 506-09 (1988) (discussing *Miree*). *Miree* did not address,

however, the validity of the third-party beneficiary claim or whether the Act at issue contained an implied right of action. 433 U.S. at 33-34. And in *American Surety Co. of New York v. Schultz*, 237 U.S. 159, 160 (1915), *see* Resp. Br. 25, the bond sued upon did not incorporate any requirement under a federal statute. Accordingly, this Court's decisions do not support the proposition that a non-party to a contract embodying a statutory requirement can bring suit to enforce that requirement absent showing an implied right of action under the statute.

2. Respondent relies on the Court's observation in *Jackson Transit* that the question presented in that case did "not fit comfortably in th[e] mold" of a private right of action case. Resp. Br. 1, 21, 36 (quoting *Jackson Transit*, 457 U.S. at 20). The Court in *Jackson Transit* explained that whether or not the statute there contained an implied right of action, "it is reasonable to conclude that Congress expected" the agreements, "like ordinary contracts, to be enforceable." 457 U.S. at 20-21. Petitioners do not dispute that it would be reasonable to conclude that Congress expected the parties to the PPA to have contract remedies to enforce the agreement. Pet. Br. 45. That conclusion does not mean, however, that Congress intended to confer enforceable rights on 340B entities that are not parties to the PPA and on which Congress conferred no private remedy under the Act. *See supra* pp. 3-7.

The government posits that the PPA is not a contract. U.S. Br. 14-21. *But cf. Mobil Oil Exploration & Producing Se., Inc. v. United States*, 530 U.S. 604, 607 (2000); Pet. App. 180a (PPA ¶ VII(g)) (providing that the PPA "shall be construed in accordance with Federal common law"). If the government is correct,

the absence of a contract dooms respondent's third-party beneficiary claim *ab initio*. But even if the PPA is enforceable as a contract, Congress required manufacturers to enter into an agreement with the Secretary, and only the Secretary. And Congress authorized the Secretary, and only the Secretary, to enforce a manufacturer's ceiling price obligations.

### C. Federal Common Law Claims Would Seriously Disrupt The 340B And Medicaid Drug Rebate Programs

1. Even were respondent correct that federal common law presumptively authorizes a cause of action for purported third-party beneficiaries unless Congress displaces that authority, Resp. Br. 2-3, 17, 20, 22, 30, 34-36, Congress plainly did so here. The 340B program and the vastly larger Medicaid program are interrelated, and together those Acts confer powerful enforcement tools on the Secretary, including audit rights, severe civil monetary penalties, and termination of the PPA and federal financial participation for the manufacturer's outpatient drugs covered under State Medicaid plans. Pet. Br. 38-39; U.S. Br. 4, 30-31.

The 340B and Medicaid Acts, taken together, establish a comprehensive and interwoven statutory scheme that vests exclusive and centralized enforcement authority with the Secretary, who has the expertise to uniformly enforce both programs. Pet. Br. 37-39, 41; U.S. Br. 29-33; Br. of PhRMA as Amicus Curiae 20-22. As the government agrees, the availability of private suits by over 14,500 covered entities to challenge any and all AMP and BP pricing decisions would seriously disrupt the administration of both the 340B and Medicaid Rebate Acts. Pet. Br. 32-42; U.S. Br. 33-34. Because Congress has

"occupied the field through the establishment of a comprehensive regulatory program supervised by an expert administrative agency," federal common law remedies are foreclosed. *City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981); *see also Northwest Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 95-99 (1981).

Common law suits would permit 340B entities to challenge the judgments used by manufacturers in calculating AMP or BP for tens of thousands of pharmaceutical products for which Medicaid rebates are paid. Br. of PhRMA as Amicus Curiae 22-23. Although respondent has not identified a drug product for which it believes it was overcharged, Pet. App. 29a, 112a, this suit purports to challenge each and every AMP and BP reported by nine large manufacturers over an eight-year putative class period. *See supra* p. 5. The burdens on manufacturers from suits by 340B entities would be staggering. For example, to produce all AMP and BP information for a sample of only three drugs per manufacturer in the first stage of discovery, the district court observed that,"[i]t is safe to say many millions were spent by defendants producing the responsive materials." Third Am. Case Management Order 1 (N.D. Cal. July 9, 2010).

It also is difficult to overstate the breadth and complexity of the pricing methodology under the 340B and Medicaid Rebate programs. *E.g.*, Pet. Br. 34-37. AMP, for example, was defined as the average price paid by wholesalers in the United States for drugs dispensed to the "retail pharmacy class of trade." 42 U.S.C. § 1396r-8(k)(1). The Medicaid Act did not define the terms "wholesalers" or "retail pharmacy class of trade." Nor did the Centers for

Medicare & Medicaid Services ("CMS") interpret those terms in regulations from the inception of the Medicaid Rebate program in 1990 through 2007.

Because AMP is an "average" of prices charged in commercial transactions, manufacturers must (1) calculate the number of drug units sold, drug unit prices, and commercial rebates or other price concessions provided for all sales of a covered drug in each reporting period; (2) determine which of those sales must be included in AMP (because they are to a customer in the "retail pharmacy class of trade") and which of those sales must be excluded from AMP (because they are to customers outside the "retail pharmacy class of trade"); and then (3) calculate the weighted average of the includable sales prices, net of any price concessions. *See, e.g.*, 72 Fed. Reg. 39,142, 39,146-49 (July 17, 2007). These calculations are even more complex because some sales are made to wholesalers, who in turn sell product to the end user. Some of those end users are retail customers while others are not. The calculation of BP also is quite complex. For example, because the "Best Price" is not simply the manufacturer's lowest price on *any* sale, but rather is the lowest *net* price to a *non-excluded* customer, difficult questions arise concerning which prices are excluded and which are not, as well as what rebates, discounts and other price concessions should be counted to determine the net price. *See, e.g.*, *id.* at 39,149-51.

As PhRMA explains in its amicus brief (at 23), manufacturers devote substantial internal and external resources to the price reporting process and invest substantial sums in sophisticated computer systems to track their sales and rebates and to calculate Medicaid rebates and 340B ceiling prices.

*See also* Pet. Br. 34. The lack of formal agency guidance from 1990 through 2007 made the AMP and BP calculation process all the more difficult. *Id.* at 34-36; Br. of PhRMA as Amicus Curiae 24-25.

Even after the Secretary issued her final rule in 2007, which comprises 104 pages of intricate, detailed, and complex guidance setting forth the categories of sales and price concessions that manufacturers must include and exclude from AMP and BP, the Secretary nevertheless vested manufacturers with discretion to make reasonable assumptions in their AMP and BP calculations in the absence of applicable agency guidance. 72 Fed. Reg. at 39,171; J.A. 78-79 (Medicaid Rebate Agreement § II(i)); Br. of the United States as Amicus Curiae at 5, *County of Santa Clara v. Astra USA, Inc.*, No. 09-15216 (9th Cir. Oct. 27, 2009) ("C.A. Gov't. Br."). Now that the Secretary's AMP regulations have been withdrawn, 75 Fed. Reg. 69,591 (Nov. 15, 2010), manufacturers confront additional questions of statutory interpretation in calculating AMP. Courts or perhaps juries in common law breach of contract actions should not be permitted to impose liability on manufacturers for making reasonable interpretations with respect to the AMP and BP treatment of potentially millions of drug transactions under highly technical and complex statutes that centralize enforcement of both programs with the Secretary.

Respondent further does not dispute that the interests of 340B entities and the Medicaid program conflict with respect to AMP. Pet. Br. 40-41. A lower AMP generally reduces the ceiling price paid by 340B entities but at the same time reduces the amount of Medicaid rebates paid to the States under the Medicaid program. *Id.*; C.A. Gov't Br. 31. As the Secre-

tary explained to the court of appeals, "if both 340B entities and states can bring separate suits over AMP calculations, there is a real possibility that manufacturers could be subject to inconsistent obligations." C.A. Gov't Br. 31-32; *see also* U.S. Br. 34.

Respondent is wrong that the conflict concerning AMP is merely "hypothetical." Resp. Br. 58. Respondent itself has alleged that petitioners miscalculated their AMPs and has sought extraordinarily extensive, burdensome, and costly discovery from manufacturers with respect to their AMP calculations. *See, e.g.*, Pet. App. 74a (respondents seek "[a]ll information . . . underlying [petitioners'] determination of AMP and BP"). States have alleged that manufacturers should have reported a *higher* AMP. *See Massachusetts v. Mylan Labs.*, 357 F. Supp. 2d 314, 321 (D. Mass. 2005). And the U.S. Department of Justice has pursued False Claims Act litigation against at least one pharmaceutical company (King Pharmaceuticals) for, among other things, allegedly misreporting its AMPs. *See* Press Release, Dep't of Justice (Nov. 1, 2005), *available at* www.justice.gov/opa/pr/2005/November/05_civ_581.html. Again, Congress, the Secretary, and manufacturers alike contemplated that the Secretary exclusively would enforce a manufacturer's pricing obligations under the 340B Act, not that manufacturers would be hauled into court by up to 14,500 different entities that have neither the expertise nor obligation to consider potentially conflicting objectives of the much larger Medicaid Rebate program.

2. Respondent downplays the above concerns by suggesting that "[t]o the extent difficult issues arise, they can be dealt with through primary jurisdiction referrals." Resp. Br. 51. But "referral to HHS would

depend on a case-by-case judicial determination, and could interfere with HHS's enforcement priorities." U.S. Br. 35 n.15 (internal citation omitted). More fundamentally, the Secretary has *exclusive* jurisdiction to enforce a manufacturer's ceiling price obligations by administering the 340B Act on a centralized, uniform basis. A common law regime of piecemeal referrals to the Secretary is not the scheme passed by Congress.

Respondent, citing by analogy the False Claims Act ("FCA"), 31 U.S.C. § 3729 *et seq.*, argues that private enforcement suits are "well-suited" to enhance the Secretary's enforcement efforts. Resp. Br. 50. The FCA, however, contains protections that do not apply to ordinary breach of contract suits. Significantly, FCA suits are subject to the control of the United States, 31 U.S.C. § 3730(c)(2)(A), and seek damages on behalf of the United States. Thus, FCA suits safeguard the interests of the United States, not interests of 340B entities that could well diverge from those of the United States. The FCA also requires the relator to allege that a defendant has "knowingly" made a "false or fraudulent claim," *id.* § 3729(a)(1), and to satisfy the heightened pleading requirements for fraud. *See* John T. Boese, *Civil False Claims and Qui Tam Actions* § 5.04 (4th ed. & Supp. 2011-1). A common law breach of contract suit contains none of those protections.

Respondent also points to the Secretary's position that the Medicaid Act does not preempt States from pursuing state law fraud claims against manufacturers. Resp. Br. 49-50, 54-55. But the issue of whether a federal statute preempts state law is distinct from the question presented here, which is whether Congress conferred on 340B entities a federal

common law right to enforce the 340B Act. *See City of Milwaukee*, 451 U.S. at 316.

Respondent also laments that Congress passed the 340B Act without giving 340B entities a right to enforce the Act in court. Resp. Br. 34. That deliberate choice by Congress is all the more reason to preclude courts from creating such remedies under common law. Congress vested the Secretary with comprehensive authority to enforce a manufacturer's drug pricing obligations. That is enough to displace a common law remedy. *City of Milwaukee*, 451 U.S. at 324. Courts may "disagree with the regulatory approach taken by the agency with responsibility," but "such disagreement alone is no basis for the creation of federal common law." *Id.* at 323.

Respondent discusses a series of FCA settlements by drug manufacturers alleging violations of the BP requirements of the Medicaid Act. Resp. Br. 9-11, 50-55. As an initial matter, those settlements go a long way in refuting respondent's insistence that federal administrative oversight and enforcement efforts have been "virtually non-existent." Resp. Br. 11; *accord id.* at 55-58. AMP and BP calculations by the pharmaceutical industry are subject not only to extensive internal controls and independent audits, but also to on-going government oversight under the Medicaid Act, qui tam actions under the FCA, a federally-funded Health Care Fraud and Abuse Control Program, 42 U.S.C. § 1320a-7c, and other statutory and regulatory requirements.

It also is important to put the FCA settlements into their proper context. The FCA imposes substantial penalties of $5,500-$11,000 per violation, treble damages, and attorney's fees. 31 U.S.C. §§ 3729(a)(1), 3730(d). Further, Section 1128B of the Social

Security Act grants the Department of Health and Human Services Office of Inspector General ("OIG") discretion to exclude drug manufacturers from federal healthcare programs where the Secretary has determined that a false or improper claim was made. *See* 42 U.S.C.§ 1320a-7(b)(7); 42 C.F.R.§ 1001.901.

Accordingly, the government has an extraordinary array of tools at its disposal to extract concessions from pharmaceutical companies even where those companies have good faith arguments against liability. Notwithstanding the comprehensive efforts by manufacturers to comply with applicable guidelines, "the evolving use by the government of the fraud and abuse laws" often has "force[d] settlements by drug and device manufacturers for conduct that was, in large part, viewed by FDA and other agencies as acceptable industry practice until DOJ and OIG began to redefine the regulatory landscape." Marc J. Scheineson & Shannon Thyme Klinger, *Lessons from Expanded Government Enforcement Efforts Against Drug Companies*, 60 Food & Drug L.J. 1, 7 (2005).

The FCA allegations cited by respondent often were premised upon manufacturers' reasonable interpretation of the complex, ambiguous, and often inconsistent regulatory regime described above. As but one example, the private-label settlements entered into by Aventis, Bayer, GlaxoSmithKline, and Bristol-Myers Squibb, *see* Resp. Br. 9, involved the judgments by those companies to exclude from their BP determinations the price charged in the sale of certain products to Kaiser, a health maintenance organization with its own drug packaging facility that relabeled the products under Kaiser's own National Drug Code ("NDC"). In 1997, CMS issued a guidance document, Rebate Release No. 29, which

instructed manufacturers to exclude from BP "sales to other manufacturers who repackage/re-label under the purchaser's NDC." CMS, Medicaid Drug Rebate Program Release No. 29 (1997), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp.

Because Kaiser sold the Aventis, Bayer, GlaxoSmithKline, and Bristol-Myers Squibb products under Kaiser's NDC, these manufacturers construed Rebate Release No. 29 to exclude their Kaiser sales from BP. CMS subsequently determined in Rebate Release Nos. 47 and 68, however, that manufacturers should include sales to re-labelers that are also HMOs in their BP calculations. CMS, Medicaid Drug Rebate Program Release No. 47 (2000) & No. 68 (2005), *available at* http://www.cms.gov/MedicaidDrugRebateProgram/03_DrugMfrReleases.asp. Far from supporting improper conduct, these settlements reflect a good faith disagreement over proper interpretation of ambiguous and conflicting guidance issued by CMS. Neither 340B entities nor juries are better positioned to make those difficult and complex judgments.

FCA settlements also often contain a recovery for 340B entities. *See* Kirsten V. Mayer, *The Medicaid/340B Program "Best Price" Enforcement Landscape*, Big Four Pharmaceutical Pricing Boot Camp 3-5 (2007). To the extent respondent complains that 340B entities received "[o]nly a small portion of those settlement dollars," Resp. Br. 9, 340B entities' expenditures are only a small fraction of Medicaid's expenditures. *Compare Medicaid Prescription Drug Reimbursement: Hearing Before the H. Energy and Commerce Subcomm. on Oversight and Investigations*, 108th Cong. 1 (2004) (testimony of Dennis Smith,

Dir. of CMS) ("In 2003, Medicaid spent more than $34 billion on prescription drugs."), *with* OIG, *Review of 340B Prices* 1 (2006) ("The 340B entities spent an estimated $3.4 billion on covered outpatient drugs in calendar year 2003.").

### D. Covered Entities Are Not Intended Third-Party Beneficiaries Under The Common Law

As discussed, by disavowing that this case turns on the Secretary's intent in entering into the PPA, respondent no longer defends the Ninth Circuit's holding that the contracting parties intended to confer enforceable rights on 340B entities. Respondent nonetheless contends that petitioners waived the issue. Resp. Br. 22, 33, 47. Respondent is wrong.

To be sure, petitioners' primary submission is that a third-party beneficiary common law action would impermissibly circumvent this Court's private right of action jurisprudence. Petitioners also have strenuously argued, however, that the contracting parties never intended the PPA to create rights in favor of non-parties. *E.g.*, Pet. Br. 30 ("[P]ermitting this challenge would 'accord . . . rights never intended by the PPA's signatories.'") (quoting C.A. Gov't Br. 13); *accord* Pet. 33 (same); Pet. Reply 5 (arguing that the decision below strayed "far from the mainstream" in holding that the contracting parties intended to create enforceable rights).

Moreover, as respondent observes, the common law would not permit this suit if it conflicted with the objectives of the 340B Act. Resp. Br. 32 (citing Restatement (Second) of Contracts § 313(1)). Petitioners consistently have argued that common law suits would conflict with Congress's judgment to vest

exclusive enforcement authority with the Secretary and would disrupt the administration of both the 340B and Medicaid Rebate Acts. Pet. Br. 32-42; Pet. 21-24; Pet. Reply 6-9. Thus, even assuming a common law action may proceed in the absence of an implied right of action, the decision below should be reversed.

* * * * *

Suits under the common law create the same separation of powers issues and disruption to the statutory scheme as suits under the statute. No matter the form in which respondent seeks to enforce the 340B Act's ceiling price provisions, Congress declined to authorize private enforcement of those provisions. That principle controls this case.

## CONCLUSION

For the foregoing reasons and the reasons stated in petitioners' opening brief, the decision below should be reversed.

Respectfully submitted,

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# AMICUS CURIAE BRIEF

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# In the Supreme Court of the United States

ASTRA USA, INC., ET AL., PETITIONERS

*v.*

SANTA CLARA COUNTY, CALIFORNIA

*ON WRIT OF CERTIORARI*
*TO THE UNITED STATES COURT OF APPEALS*
*FOR THE NINTH CIRCUIT*

## BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

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## QUESTION PRESENTED

Section 340B of the Public Health Service Act, 42 U.S.C. 256b, instructs the Secretary of Health and Human Services to enter into a Pharmaceutical Pricing Agreement (PPA) with drug manufacturers, in which the manufacturers pledge to offer discounted prices to certain healthcare providers known as "340B entities."

Respondent operates several 340B entities, and it alleges that petitioners—drug manufacturers that entered into the PPA—improperly charged prices higher than those permitted under the PPA. The question presented is whether respondent may bring a third-party breach-of-contract action to enforce petitioners' obligations under the 340B Program.

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42 U.S.C. 1396r-8(c) ..... 2, 15
42 U.S.C. 1396r-8(c)(1)(A) ..... 3
42 U.S.C. 1396r-8(c)(1)(B) ..... 3
42 U.S.C. 1396r-8(c)(1)(C) ..... 3
42 U.S.C. 1396r-8(c)(2) ..... 3
42 U.S.C. 1396r-8(c)(3) ..... 3
42 U.S.C. 1396r-8(k)(1)(A) ..... 3
Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 ..... 2, 12
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Social Security Act, Tit. XIX, 42 U.S.C. 1396 *et seq.* ..... 1
42 U.S.C. 1396a (2006 & Supp. II 2008) ..... 2
42 U.S.C. 1396d(a)(12) ..... 2
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42 U.S.C. 256b(a)(2) ..... 5, 15
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42 U.S.C. 256b(a)(5) ..... 16, 19, 26
42 U.S.C. 256b(a)(5)(A) ..... 19
42 U.S.C. 256b(b) ..... 15
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42 U.S.C. 1437f ..... 23
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61 Fed. Reg. (1996):
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pp. 65,412-65,413 ..... 6
75 Fed. Reg. (2010):
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p. 57,233 ..... 8
pp. 69,591-69,597 ..... 3, 18
Government Accountability Office, *Prescription Drugs: Oversight of Drug Pricing in Federal Programs* (2007) ..... 6, 7, 29, 32
H.R. Rep. No. 384, 102d Cong., 2d Sess. Pt. 2 (1992) ..... 4
David H. Kreling, *The Market for Pharmaceuticals: The Big Picture*, *in* Handbook of Pharmaceutical Public Policy (Thomas R. Fulda & Albert I. Wertheimer eds., 2007) ..... 27
9 John E. Murray, Jr., *Corbin on Contracts* (rev. ed. 2007) ..... 25
Office of the Inspector General, HHS:
*Deficiencies in the Oversight of the 340B Drug Pricing Program* (Oct. 2005) ..... 28, 32
*Review of 340B Prices* (July 2006) ..... 6, 27
Restatement (Second) of Contracts (1981) ..... 24, 25

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13 Samuel Williston & Richard A. Lord, *A Treatise on the Law of Contracts* (4th ed. 2000) ..... 24

# In the Supreme Court of the United States

No. 09-1273

ASTRA USA, INC., ET AL., PETITIONERS

*v.*

SANTA CLARA COUNTY, CALIFORNIA

*ON WRIT OF CERTIORARI*
*TO THE UNITED STATES COURT OF APPEALS*
*FOR THE NINTH CIRCUIT*

## BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING PETITIONERS

### INTEREST OF THE UNITED STATES

This case concerns the pharmaceutical pricing program established in 42 U.S.C. 256b and known as the 340B Program. The Department of Health and Human Services (HHS) administers the 340B Program, as well as the closely related Medicaid Rebate Program, see 42 U.S.C. 1396r-8. Accordingly, the United States has a substantial interest in the issues presented in this case.

### STATEMENT

1. a. The Medicaid program, established by Title XIX of the Social Security Act (the Medicaid Act), 42 U.S.C. 1396 *et seq.*, is a cooperative federal-state program that provides medical assistance to certain low-

income individuals.[1] *Harris* v. *McRae*, 448 U.S. 297, 301 (1980). In order to participate in the Medicaid program, a State must have a plan for medical assistance that has been approved by HHS's Centers for Medicare & Medicaid Services (CMS), which administers the federal Medicaid program. 42 U.S.C. 1396a (2006 & Supp. II 2008). As part of a State's Medicaid plan, a State may offer outpatient prescription drug coverage. 42 U.S.C. 1396d(a)(12).

The Medicaid Rebate Program, established in 1990, establishes the framework governing Medicaid coverage of prescription drugs. See Omnibus Budget Reconciliation Act, Pub. L. No. 101-508, § 4401, 104 Stat. 1388-143 (codified as amended at 42 U.S.C. 1396r-8). Drug manufacturers seeking to have their drugs covered by Medicaid must enter into agreements with HHS to provide rebates to the States on their sales of prescription drugs covered by Medicaid. 42 U.S.C. 1396r-8(a)(1); see *Pharmaceutical Research & Mfrs. of Am.* v. *Walsh*, 538 U.S. 644, 652 (2003).

The terms of each Medicaid rebate agreement are dictated by statute, and they obligate the manufacturer to pay specified rebates to the States, determined pursuant to a formula set forth in Section 1396r-8(c). For single-source and innovator multiple-source drugs (essentially, brand-name drugs), the rebate due on each drug unit is typically the difference between the "average manufacturer price" (AMP) and the manufacturer's

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[1] The Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, 124 Stat. 119 (2010), made significant changes to the Medicaid Act and the 340B Program. Unless otherwise noted, references to the Medicaid and 340B statutes are to the pre-PPACA law in effect at the time of the court of appeals' decision.

"best price" (Best Price), or a defined percentage of AMP, whichever is greater. 42 U.S.C. 1396r-8(c)(1)(A), (B), (C) and (c)(2). For other drugs, the rebate is a percentage of AMP. 42 U.S.C. 1396r-8(c)(3).

Until October 1, 2010, a drug's AMP was defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade."[2] 42 U.S.C. 1396r-8(k)(1)(A). A drug's Best Price is generally the "lowest price available from the manufacturer during [the relevant time period] to any" private purchaser or governmental entity. See 42 U.S.C. 1396r-8(c)(1)(C).

Manufacturers are required to calculate AMP and Best Price and report those figures to CMS, which then uses these data to calculate the unit rebate amount for each drug. See 42 U.S.C. 1396r-8(b)(3)(A). CMS has promulgated comprehensive regulations instructing manufacturers on how to calculate AMP and Best Price. See 42 C.F.R. 447.500 to 447.520.[3] Because the reported AMP and Best Price are sensitive trade information, the Medicaid Act prohibits HHS from disclosing the information "in a form which discloses the identity of a specific manufacturer * * * [, or] prices charged for drugs by such manufacturer," except in enumerated situations. 42 U.S.C. 1396r-8(b)(3)(D).

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[2] Effective October 1, 2010, the PPACA amends the definition of AMP by tying its calculation to prices charged to "retail community pharmacies." Pub. L. No. 111-148, § 2503(a)(2) and (d), 124 Stat. 310, 312.

[3] In order to comply with the PPACA, CMS has withdrawn its regulations pertaining to the definition of AMP, and will issue regulations regarding the PPACA's amended definition. 75 Fed. Reg. 69,591-69,597 (2010).

b. The Medicaid Act and the rebate agreement provide HHS with comprehensive measures to enforce manufacturers' statutory obligation to accurately report AMP and Best Price to CMS. HHS may audit manufacturers' calculations, 42 U.S.C. 1396r-8(b)(3)(A)-(B), may impose monetary penalties for knowing violations, 42 U.S.C. 1396r-8(b)(3)(B)-(C), and may seek other remedies provided by law, 42 U.S.C. 1396r-8(b)(3)(C)(ii). Under the Medicaid rebate agreement, CMS also may require manufacturers to correct erroneous data and make additional rebate payments to States. J.A. 81. Finally, CMS may terminate a manufacturer's participation in the program because of "violation[s] of * * * the agreement or other good cause." 42 U.S.C. 1396r-8(b)(4)(B)(i).

2. a. The 340B Program is closely related to the Medicaid Rebate Program. In 1992, Congress became concerned that manufacturers, in an attempt to raise the Best Price figures for their drugs under Medicaid and lower their rebate payments to States, had reduced the discounts that they had been giving to safety-net providers that provide health care to underserved individuals. See H.R. Rep. No. 384, 102d Cong., 2d Sess. Pt. 2 at 10-12 (1992). Congress responded by creating the 340B Program to govern the drug prices that manufacturers may charge such entities. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4967.

Codified at 42 U.S.C. 256b, the 340B statute directs HHS to enter into a Pharmaceutical Pricing Agreement (PPA) with each drug manufacturer that chooses to participate in the Program. See 42 U.S.C. 256b(a). Manufacturers who do not opt into the 340B Program lose eligibility for Medicaid coverage of their drugs. See 42

U.S.C. 1396r-8(a)(1) and (5). Section 256b(a)(1) requires that the PPA obligate manufacturers to charge healthcare providers that are listed as "covered entities" (also known as "340B entities") prices that do not exceed the "ceiling price." 42 U.S.C. 256b(a)(1)-(2); see also Pet. App. 170a-171a. Section 256b defines the ceiling price for each drug with reference to the drug's AMP and Best Price. 42 U.S.C. 256b(a)(1)-(2). If a manufacturer overcharges covered entities, HHS may terminate the manufacturer's participation in the 340B Program. 42 U.S.C. 1396r-8(b)(4)(B)(v).

The PPA incorporates Section 256(b)'s requirements.[4] It provides that "[p]ursuant to requirements under section 340B of the Act, the Manufacturer agrees" to charge covered entities no more than the ceiling price described in Section 256b(a), based on the pricing data "reported * * * to the Secretary in accordance with the Manufacturer's responsibilities under [S]ection [1396r-8(b)(3)] of the [Medicaid Act]." Pet. App. 170a. The PPA also requires manufacturers to provide HHS with access to records to assure compliance with the pricing rules, and provides that manufacturers may invoke an informal dispute resolution process to resolve allegations that covered entities have sought duplicative discounts or otherwise violated their obligations under Section 256b(a)(5). *Id.* at 171a-175a. The PPA also permits HHS to invoke an adjudication process when it believes that a manufacturer has not complied with its obligations. *Id.* at 174a.

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[4] The language of the PPA has been revised over time, but the revisions are immaterial to this litigation. This brief relies on the version of the PPA reprinted at Pet. App. 165a-181a.

b. Within HHS, the 340B Program is administered by the Health Resources and Services Administration (HRSA). HRSA has established a voluntary dispute resolution process to resolve the disputes referred to in the PPA, and also to resolve "certain [other] disputes between manufacturers and covered entities concerning compliance with the provisions of" Section 256b. 61 Fed. Reg. 65,411 (1996). Covered entities that believe that a manufacturer is charging a price in excess of the ceiling price may invoke that procedure. *Id.* at 65,412. Upon finding that a manufacturer has failed to comply with its obligations, HRSA may order refunds to covered entities, Pet. App. 174a, or terminate the agreement. *Ibid.*; 61 Fed. Reg. 65,412-65,413.

c. In practice, the 340B Program generally works as follows: Manufacturers are responsible for calculating the ceiling price for each drug based on the AMP and Best Price that they have reported to CMS, as well as the instructions in Section 256b(a). Most drug sales to covered entities are routed through wholesalers, see Office of the Inspector General (OIG), HHS, *Review of 340B Prices* 2 (July 2006) (*340 Report*), so manufacturers generally instruct wholesalers to charge covered entities the manufacturer-calculated ceiling price. The wholesalers do so, often adding a distribution fee.

Independently, HRSA calculates the ceiling price for each drug based on the reported AMP and Best Price. *340B Report* 3; Gov't Accountability Office, *Prescription Drugs: Oversight of Drug Pricing in Federal Programs* 5 (2007) (*Oversight Report*). HRSA's calculated ceiling price should be equal to the ceiling price that the manufacturer provided to wholesalers. But the Medicaid Act's confidentiality provision prohibits HHS from re-

vealing manufacturers' reported AMP and Best Price, as well as the ceiling price that HRSA has calculated based on those figures. See 42 U.S.C. 1396r-8(b)(3)(D). As a result, although covered entities naturally are aware of the price that they have been charged for each drug, *i.e.*, the price that the manufacturer claims is the correct ceiling price, they have no way of verifying whether the manufacturer's selling price accords with HRSA's calculations, or whether it is based on accurate AMP and Best Price figures. *Oversight Report* 5 & n.11. A covered entity may, however, ask that HRSA verify that the entity is not being overcharged. HRSA has informed this Office that although covered entities do not often utilize this procedure, when they do, HRSA is often able to resolve overcharges informally with the manufacturers.

3. In March 2010, Congress enacted the Patient Protection and Affordable Care Act (PPACA), which made significant changes in the 340B Program. Pub. L. No. 111-148, §§ 7101-7102, 124 Stat. 821-827. In addition to increasing the scope of the program by adding new categories of covered entities, the PPACA directs HHS to institute a comprehensive administrative process to adjudicate and remedy violations of the 340B Program's requirements for purchases after January 1, 2010, § 7102(a), 124 Stat. 823-827, subject to judicial review pursuant to the Administrative Procedure Act (APA), 5 U.S.C. 701 *et seq.* The PPACA also instructs HHS to develop procedures by which manufacturers may be required to refund overcharges to covered entities and to pay civil monetary penalties for intentional violations. § 7102(a), 124 Stat. 824.

To comply with the PPACA's mandate, HHS has issued advance notices of proposed rulemaking soliciting

comments on HHS's development of the civil monetary penalty scheme and the administrative adjudication process. See 75 Fed. Reg. 57,230 (2010); *id.* at 57,233.

4. a. In 2005, respondent, which operates several 340B entities, brought this action in California state court on behalf of a putative class of 340B entities. Pet. App. 6a; J.A. 1, 28-30, 56. Respondent alleged that petitioners—drug manufacturers that participate in the 340B Program—had charged respondent prices that exceeded the ceilings established by the PPA. J.A. 47-49, 50-56. Among other claims, respondent asserted a breach-of-contract action premised on its purported status as an intended third-party beneficiary of the PPA. J.A. 63-65. After the case was removed to federal court, the district court dismissed the complaint, concluding, among other things, that the PPA did not reflect any intent to confer enforcement rights on 340B entities. Pet. App. 98a, 113a-119a.

b. The court of appeals reversed and remanded. Pet. App. 36a. The court first concluded that respondent was an intended third-party beneficiary of the PPA because the agreement was executed for the purpose of regulating the prices that petitioners may charge covered entities. *Id.* at 41a-43a. In the court's view, it necessarily followed that respondent had the right to bring suit under the PPA, because "the right to sue inheres in one's status as an intended beneficiary." *Id.* at 39a, 41a-50a. Permitting the suit would be consistent with the statutory scheme despite the lack of any private right of action to enforce Section 256b itself, the court reasoned, because Congress's failure to accord 340B entities statutory remedies reflected its intent not to "displace" any federal common law enforcement rights arising from the

PPA. *Id.* at 51a-54a. Finally, the court held that referral to HHS under the doctrine of primary jurisdiction was unnecessary because the PPA entitled covered entities "only to the [AMP] *reported* to the Secretary," and respondent "cannot claim that the reported figure was itself somehow erroneous" under HHS's regulations. *Id.* at 57a.

c. On remand, the district court held that the court of appeals' opinion precluded respondent from challenging the accuracy of petitioners' calculations of AMP and Best Price. Pet. App. 90a. The court of appeals accepted an interlocutory appeal from that ruling, see 28 U.S.C. 1292(b), and invited the United States to file an amicus brief. Pet. App. 90a.

The government argued, *inter alia*, that the PPA requires manufacturers to calculate the ceiling price based on AMP and Best Price figures correctly reported in accordance with the Medicaid rebate framework. Gov't C.A. Br. 15-17. The government explained, however, that permitting respondents to challenge those figures or ceiling prices in a third-party beneficiary suit would conflict with the PPA and the statutory scheme. *Id.* at 17-21. Finally, the government stated that, given HHS's expertise in the comprehensive framework governing AMP and Best Price, referring the dispute to HHS under the primary jurisdiction doctrine might be appropriate once the nature of respondent's allegations became clearer. *Id.* at 22-32.

The court of appeals reissued its original opinion with a revised discussion of primary jurisdiction that omitted the suggestion that ceiling prices were tied to reported AMP and Best Price. Pet. App. 2a, 27a-29a.

## SUMMARY OF ARGUMENT

The court of appeals' ruling that 340B entities may enforce manufacturers' obligations under the 340B Program through breach-of-contract suits is inconsistent with the statutory framework and, in particular, Congress's decision to vest enforcement authority in HHS.

I. The PPACA materially alters the 340B statutory framework by establishing a comprehensive administrative procedure to resolve claims by covered entities and to provide refunds and other remedies for violations. This procedure is intended to be exclusive, and although it will not apply to the claims at issue in this case, its enactment demonstrates that Congress regards the 340B Program as essentially statutory and regulatory—not contractual—in nature.

II. The court of appeals erred in treating the PPA as a transactional contract that can give rise to third-party beneficiary rights. The PPA is a regulatory mechanism that embodies the relevant provisions of the Medicaid and 340B Acts, including the price calculation rules that respondent alleges petitioners have violated, with respect to manufacturers that have opted in to the 340B Program. Manufacturers' rights and obligations flow from the statutory framework, not from bargained-for contract terms that have independent legal significance. As a result, the PPA does not give rise to enforceable third-party-beneficiary rights through the operation of the contract-law principles that might apply to an ordinary transactional contract. Respondent's entitlement to enforce the PPA must therefore arise from the statute, but as respondent acknowledged below, the 340B Act does not provide a right of action.

III. Even if the PPA is viewed as a traditional bilateral contract, the court of appeals erred in concluding that the PPA creates enforceable third-party beneficiary rights. The question whether a contract entered into by an agency creates enforceable third-party beneficiary rights depends on two inquiries: first, Congress must have authorized the agency to confer contract-enforcement rights on third parties; and second, the agency must have done so in the particular contract at issue. Here, even if HHS has the authority to confer third-party beneficiary rights in the PPA, there can be no question that it has not done so. The PPA's text demonstrates that the parties did not intend to permit potentially thousands of covered entities to bring suits alleging errors in manufacturers' price calculations. Construing the PPA to confer third-party rights would also be inconsistent with the statutory framework. The Medicaid Act's confidentiality provision bars covered entities from obtaining the information that would be necessary to determine whether manufacturers have violated their obligations. Moreover, the Medicaid Act and Section 256b contain a number of provisions that vest enforcement authority in HHS. That reflects Congress's intent that HHS should be permitted to determine the manufacturers' obligations in the first instance, in light of its expertise in, and responsibility for, both programs.

## ARGUMENT

### I. THE PATIENT PROTECTION AND AFFORDABLE CARE ACT ESTABLISHES A COMPREHENSIVE REMEDIAL SCHEME THAT, ONCE IMPLEMENTED, WILL PROVIDE THE EXCLUSIVE REMEDY FOR COVERED ENTITIES' OVERCHARGE CLAIMS

The court of appeals adjudicated the question presented—whether covered entities are intended third-party beneficiaries who may enforce drug manufacturers' obligations under the 340B Program—in light of the statutory framework in place at the time. Subsequent to the court's decision, Congress enacted the PPACA, which directs HHS to establish a comprehensive adjudicative and remedial framework to govern overcharge claims by 340B entities. See PPACA, Pub. L. No. 111-148, 124 Stat. 119. That framework will henceforth provide the exclusive remedy for covered entities.

Thus, with respect to claims relating to drugs purchased on or after January 1, 2010, § 7101(e), 124 Stat. 823, HHS must develop procedures to perform audits of manufacturers' reported ceiling prices; provide covered entities with remedies for "overcharges and other violations of the discounted pricing requirements"; and implement a civil monetary penalty system for knowing violations. § 7102(a), 124 Stat. 823-827. HHS also must institute an administrative adjudication process to resolve claims by covered entities (and manufacturers), and must develop procedures to resolve such claims expeditiously; to permit covered entities to obtain some discovery of information from manufacturers and third parties; and to permit joinder of claims and parties.

*Ibid.* The agency's resolution of claims is binding and subject to judicial review under the APA. *Ibid.*

This Court has held that when Congress establishes an administrative remedial scheme to adjudicate claims under a statute, subject to judicial review of the agency's decision, "Congress has allocated initial review to an administrative body" and has demonstrated its intent "to direct ordinary challenges under [the statute] to a single review process." *Thunder Basin Coal Co.* v. *Reich*, 510 U.S. 200, 207-209, 211-213 (1994). The PPACA's review provisions reflect just this intent, by according HHS the initial opportunity to apply its expertise in determining manufacturers' obligations under the statutory framework, and by providing broad authority to remedy violations. See *id.* at 207-208.

Respondent's breach-of-contract claim is precisely the type of claim that Congress intended should be channeled through the new review process in the future. Claims that manufacturers have failed to properly calculate AMP, Best Price, and the ceiling price "at root require interpretation of the parties' rights and duties under" the Medicaid Act, Section 256b, and HHS's regulations, thus "fall[ing] squarely within [HHS's] expertise." *Thunder Basin*, 510 U.S. at 214. Permitting covered entities instead to bring a breach-of-contract action directly in court would therefore be inconsistent with congressional intent underlying the new comprehensive framework. See *Shalala* v. *Illinois Council on Long Term Care, Inc.*, 529 U.S. 1, 13 (2000) (according the agency an "opportunity to apply, interpret, or revise policies, regulations, or statutes without possibly premature interference by different individual courts" is particularly important in the context of a complex regula-

tory program). Moreover, Congress's provision of the administrative adjudication scheme, and its corresponding preclusion of claims that bypass that scheme, will necessarily be incorporated in the PPA, so any enforcement rights that respondent might have under the PPA will be limited to seeking relief in accordance with the statutory scheme. Cf. *United States* v. *Erika, Inc.*, 456 U.S. 201, 211 n.14 (1982) (statutory preclusion of review would be incorporated in agreements under the statute, and therefore would preclude a third-party beneficiary suit).

Although the administrative review framework to be established under the PPACA will not apply to the claims at issue in this case, the enactment of that framework demonstrates that Congress regards the 340B Program as essentially statutory and regulatory—not contractual—in nature. See pp. 14-21, *infra*. Suits by covered entities on a contractual third-party-beneficiary theory are out of place under such a program. As we explain below, the statutory and regulatory nature of the 340B Program was evident prior to enactment of the PPACA, and likewise provides no basis for respondent's suit on a contractual third-party-beneficiary theory.

## II. THE PPA DOES NOT CREATE CONTRACTUAL RIGHTS IN REGULATED ENTITIES BECAUSE IT IS A REGULATORY MECHANISM OF IMPLEMENTING THE STATUTORY SCHEME WITH RESPECT TO DRUG MANUFACTURERS THAT CHOOSE TO PARTICIPATE

The court of appeals viewed the PPA as an ordinary bilateral contract between the government and drug manufacturers, and therefore assumed that the PPA gives rise to ordinary contractual relationships between

the government and manufacturers, and with covered entities as intended third-party beneficiaries. Pet. App. 8a-13a. This conception misapprehends the nature of the PPA and its function within the statutes that Congress has enacted in this area. The PPA "cannot be viewed in the same manner as a bilateral contract governing a discrete transaction." *Bennett* v. *Kentucky Dep't of Educ.*, 470 U.S. 656, 669 (1985). Rather, the PPA is part of the regulatory program established by Section 256b: it incorporates the terms and conditions set forth in Section 256b and the Medicaid Rebate Program, 42 U.S.C. 1396r-8, and applies them to manufacturers that opt to participate in the 340B Program. The obligations imposed by the PPA are therefore statutory and regulatory—not contractual—in nature, and the PPA does not give rise to enforceable contractual rights in manufacturers or in covered entities as third-party beneficiaries.

A. The 340B Program is structured as an opt-in program in which drug manufacturers may voluntarily choose to participate. Section 256b(a)(1) directs HHS to "enter into an agreement with each manufacturer of covered drugs" that decides to participate. 42 U.S.C. 256b(a)(1). The agreement must require the manufacturer to charge covered entities a price that "does not exceed" the ceiling price, which the statute defines as the AMP reduced by the rebate percentage, calculated in accordance with cross-referenced provisions of the Medicaid Act. See 42 U.S.C. 256b(a)(1)-(2) and (b), 1396r-8(c). The remainder of Section 256b sets forth the other conditions of the 340B Program. The statute defines the class of covered entities eligible to receive discounts under the 340B Program; prohibits covered enti-

ties from, among other things, seeking duplicative discounts; and establishes compliance procedures. 42 U.S.C. 256b(a)(4) and (5). In addition, the Medicaid Act gives HHS the authority to terminate manufacturers' agreements under the 340B Program, see 42 U.S.C. 1396r-8(b)(4)(B)(v), and requires HHS to keep confidential any manufacturer information that is reported to HHS under the Medicaid Rebate Program and used in the 340B Program, see 42 U.S.C. 1396r-8(b)(3)(D).

B. In order to implement Section 256b, HHS created the PPA, which manufacturers must sign in order to participate in the 340B Program. See 58 Fed. Reg. 27,291 (1993). The PPA's primary terms incorporate the statutory calculation methods and reporting requirements established by Section 256b. Specifically, the PPA provides that "[p]ursuant to requirements under section 340B of the Act, the Manufacturer agrees" to charge covered entities the ceiling price described in Section 256b(a), based on the pricing data "reported * * * to the Secretary in accordance with the Manufacturer's responsibilities under [S]ection [1396r-8(b)(3)] of the [Medicaid Act]." Pet. App. 170a.[5] The PPA thus incorporates manufacturers' statutory obligation to accurately report AMP and Best Price in accordance with the standards set forth in the Medicaid Act and its regulatory framework, and also incorporates Section 256b(a)(1)'s requirement that manufacturers calculate

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[5] Manufacturers also agree to certain recordkeeping requirements to permit HHS to verify compliance; for the most part, these requirements are duplicative of manufacturers' obligations under the Medicaid Rebate Program. See 42 U.S.C. 1396r-8(b)(3)(A), 42 C.F.R. 447.510(f); Pet. App. 171a.

the statutory ceiling price based on the accurately reported AMP and Best Price.

Respondent's claims in this case underscore that the manufacturers' obligations under the PPA arise from the statutory framework, rather than any separate terms created by agreement between the manufacturer and HHS. Respondent alleges that petitioners breached the PPA by reporting improperly calculated AMP and Best Price and charging more than the 340B ceiling price, see J.A. 41-42, 44-45; Br. in Opp. 8-10—not that petitioners violated any independent substantive obligation arising only from the PPA. When a party's obligations under an agreement with an agency simply embody statutory requirements, the natural inference is that "Congress did not intend that contract principles govern the interpretation of the relationship between the Secretary" and regulated entities, and the agreement does not give rise to contractual rights in the regulated parties. *Rendleman* v. *Bowen*, 860 F.2d 1537, 1542 (9th Cir. 1988); see *Aiken* v. *United States*, 4 Ct. Cl. 685, 692 (1984); *American Hosp. Ass'n* v. *Schweiker*, 721 F.2d 170, 182-183 (7th Cir. 1983), cert. denied, 466 U.S. 958 (1984).

Moreover, the PPA's terms, unlike those of an ordinary transactional contract, remain subject to Congress's and HHS's authority to alter them by enacting legislation or promulgating regulations. See *Bowen* v. *Public Agencies Opposed to Soc. Sec. Entrapment*, 477 U.S. 41, 55 (1986) (*POSSE*) (because "Congress retained authority to amend" a provision in a federal-state agreement, the provision did not create vested contractual rights); *National R.R. Passenger Corp.* v. *Atchison, Topeka & Santa Fe Ry.*, 470 U.S. 451, 465 (1985) (*Atchi-*

*son*). For example, Congress has altered manufacturers' obligations under the PPA by expanding the statutory definition of "covered entity" in Section 256b(a)(4). See, *e.g.*, Pub. L. No. 111-148, § 7101, 124 Stat. 821-823; Pet. App. 167a (defining "covered entity" as the entities listed in Section 256b(a)(4)). Similarly, the method by which manufacturers are required to calculate the ceiling price under the PPA can be altered by amending the provisions of the Medicaid Rebate Program, see *id.* at 170a; 42 U.S.C. 1304, or CMS's regulations, see, *e.g.*, 75 Fed. Reg. at 69,591-69,597 (withdrawing regulation governing AMP).

The terms of the PPA, moreover, are not the product of negotiation between the parties—the PPA is a form agreement to which manufacturers must agree in full. Compare *Rendleman*, 860 F.2d at 1541. The PPA's provisions also do not reflect an exchange of reciprocal obligations or of items or services of value between the parties (or any other bargained-for consideration); for example, the information-sharing and other obligations of HHS that are recited in the PPA are intrinsic to the agency's responsibility for administering the statutory scheme. See Pet. App. 172a. Thus, the primary benefit to the manufacturer arising from the PPA is statutory: under the Medicaid Act, a manufacturer's drugs will not be included in the Medicaid Rebate Program unless the manufacturer opts into the 340B Program. See 42 U.S.C. 1396r-8(a)(1) and (5).

Similarly, HHS's power to enforce obligations incorporated in the PPA has the character of administrative enforcement. The PPA reiterates HHS's statutory right to terminate the agreement if it determines that a manufacturer has charged a price that exceeds the ceiling

price or has otherwise failed to comply with statutory requirements.[6] See Pet. App. 174a; 42 U.S.C. 1396r-8(b)(4)(B)(v). The PPA also provides that HHS may order a manufacturer to reimburse a covered entity for "discounts withheld," Pet. App. 174a, and provides for informal agency adjudication of manufacturers' claims against covered entities for violating statutory provisions in Section 256b(a)(5). *Id.* at 173a-174a; 42 U.S.C. 256b(a)(5)(A). As noted above, Congress confirmed in the PPACA that the drug manufacturers' obligations are statutory, and that the overall 340B framework is regulatory, not contractual, by directing HHS to create a formal, mandatory adjudication process to resolve the claims of both manufacturers and covered entities, subject to APA review. See pp. 12-14, *supra*.

C. In sum, the PPA is the mechanism by which Congress and HHS effectuate "regulatory policy," rather than "a contractual arrangement" that gives rise to bargained-for contractual rights in the regulated parties. *Atchison*, 470 U.S. at 465; see *POSSE*, 477 U.S. at 55. In analogous situations, courts have concluded that Congress's use of an agreement to facilitate participation in, and mark entry into, a regulatory scheme does not create contractual rights in the regulated entities.

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[6] The United States also may sue to enforce manufacturers' compliance with the terms and conditions of the 340B Program as an incident to their receipt of federal Medicaid funds. See *United States* v. *Marion County Sch. Dist.*, 625 F.2d 607, 609-610 (5th Cir. 1980), cert. denied, 451 U.S. 910 (1981); cf. *Bennett*, 470 U.S. at 669 (federal grant program was not purely contractual in nature, but the government may seek reimbursement of federal funds when State has violated its obligations); *Bell* v. *New Jersey*, 461 U.S. 773, 793-794 (1983) (White, J., concurring) (government is entitled to enforce funding conditions).

See, *e.g.*, *id.* at 55 (termination provision in federal-state agreements to provide Social Security benefits to state employees under 42 U.S.C. 418 was "part of a regulatory program"); *Hollander* v. *Brezenoff*, 787 F.2d 834, 838-839 (2d Cir. 1986) ("Congress—when enacting [S]ection 1396a(a)(27) of the Social Security Act—did not aim to create a contract cause of action for the benefit of providers, but simply sought to facilitate the processing and transmission of information by providers supplying services under the Medicaid plan."); *Memorial Hosp.* v. *Heckler*, 706 F.2d 1130, 1136-1137 (11th Cir. 1983), cert. denied, 465 U.S. 1023 (1984); *Rendleman*, 860 F.2d at 1542; *American Hosp. Ass'n*, 721 F.2d at 182-183; *Aiken*, 4 Ct. Cl. at 692. It follows that the PPA does not give rise to enforceable third-party beneficiary rights through the operation of contract-law principles.

This conclusion is buttressed by the well-established principle that statutory benefits under the Social Security Act (of which the Medicaid Act is a part) do not give rise to contractual rights in program beneficiaries and participating entities, absent a clear indication of congressional intent to incorporate contract law. See *POSSE*, 477 U.S. at 52; *Flemming* v. *Nestor*, 363 U.S. 603, 608-611 (1960); cf. *United States R.R. Ret. Bd.* v. *Fritz*, 449 U.S. 166, 174 (1980). This principle flows from Congress's need to have continuing flexibility in adjusting benefits and modifying the programs in response to changing conditions. See *Flemming*, 363 U.S. at 610-611. There is no reason to think that Congress would eschew such flexibility in the 340B Program. Congress's use of an agreement as a regulatory mechanism does not itself suggest that Congress intended to provide, *sub silentio*, for the conferral of contract rights on

manufacturers and thousands of 340B entities. See, *e.g.*, *POSSE*, 477 U.S. at 45; *Hollander*, 787 F.2d at 838-839.

Thus, if respondent has any right to enforce petitioners' obligations under the 340B Program, that right must arise from the statute or from regulations promulgated pursuant to a congressional grant of authority, not from the imposition of non-textual contract-law principles on the 340B Program and the PPA. See *Alexander* v. *Sandoval*, 532 U.S. 275, 291 (2001). As respondent conceded below, there is no private right of action to enforce Section 256b. See Pet. App. 50a. The recent amendments to Section 256b, directing HHS to create an administrative adjudication process, confirm Congress's intent that drug manufacturers' obligations be enforced in the first instance by the agency, not a court. Respondent therefore may not privately enforce petitioners' obligations under the 340B Program and the PPA.

## III. EVEN IF THE PPA IS REGARDED AS A CONTRACT, RESPONDENT DOES NOT HAVE A THIRD-PARTY BENEFICIARY RIGHT TO ENFORCE IT

For the reasons discussed above, the court of appeals erred in analyzing the PPA as a run-of-the-mine contract that can serve as a source of third-party beneficiary enforcement rights. Even taken on its own terms, however, the court's decision is incorrect. Viewed as a contract, the PPA does not confer on 340B entities the right to enforce manufacturers' obligation to charge the correct ceiling price. The PPA does not manifest the requisite intent to accord enforcement rights to 340B entities, and construing the agreement to do so would be inconsistent with the statutory scheme and harmful to

HHS's administration of the 340B and Medicaid Rebate Programs.

### A. The Existence Of Third-Party Beneficiary Rights Turns On Congressional Authorization And The Agency's Intent In Entering Into The Contract

When Congress authorizes an agency to enter into a contract, the question whether third parties may sue to enforce the contract depends on two related inquiries. First, Congress must have authorized the contracting agency to create third-party rights in the contract at issue. Second, the agency must have exercised its statutory authority by manifesting an intent to permit third parties to enforce the contract.

1. When Congress confers on an agency the authority to enter into contracts to implement a statute, Congress may also confer on the agency the authority to agree that third parties may enforce the contract. Cf. *Hercules, Inc.* v. *United States*, 516 U.S. 417, 426-428 (1996) (agency's authority to agree to specific contract terms is limited by statute). Whether Congress has conferred that authority on the agency is a question that is related to, but distinct from, the question whether Congress has rendered the statute itself directly enforceable through an express or implied right of action. Congress might reasonably decide that although a statute should not be directly enforceable by private parties, the agency should have discretion to grant third parties the right to enforce specific provisions of a contract entered into pursuant to the statute. Cf. *Sandoval*, 532 U.S. at 291 ("when a statute has provided a general authorization for private enforcement of regulations," an agency may be able to provide such rights). Whether Congress

has conferred on the agency the authority to create enforceable third-party beneficiary rights in a contract executed pursuant to a federal statute is a question of congressional intent with respect to the statute and the contract at issue.[7] See *Jackson Transit Auth.* v. *Local Div. 1285*, 457 U.S. 15, 22 (1982).

Although the absence of an express or implied right of action under the statute itself need not be dispositive of the agency's authority to create third-party contract enforcement rights, it is certainly relevant. That is particularly true when the contract simply incorporates statutory obligations, such that a third-party suit to enforce the contract would in essence seek to enforce the requirements imposed by the statute. Parties may privately enforce federal statutes only to the extent authorized by Congress, see *Mertens* v. *Hewitt Assocs.*, 508 U.S. 248, 255 n.5 (1993), and the factors that can lead a court to determine that a direct private right of action should not be inferred are relevant to the question whether Congress intended to permit the agency to grant third-party beneficiary rights by contract. For instance, when the lack of a right of action reflects Congress's intent that enforcement of the statutory scheme should be vested only in the government, and a third-party suit to enforce the contract would simply enforce statutory terms, permitting such a suit would have the effect of allowing third parties to circumvent Congress's decision not to permit private enforcement of the stat-

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[7] This individualized inquiry is particularly necessary in view of the varying contexts in which Congress grants agencies the authority to enter into agreements that contain terms pertaining to third parties. See, *e.g.*, 42 U.S.C. 1437f; 49 U.S.C. 5333(b); 38 U.S.C. 4212; 42 U.S.C. 418.

ute. In that situation, an agency's granting of third-party contract rights would be inconsistent with congressional intent. See *Erika*, 456 U.S. at 211 n.14.

2. When Congress has delegated to the agency the authority to confer third-party contract enforcement rights, the existence of those rights then turns on whether the agency has exercised its authority in the contracts at issue. Cf. *Aluminum Co. of Am.* v. *Central Lincoln Peoples' Util. Dist.*, 467 U.S. 380, 400 (1984) (agency has discretion to determine terms of contract, consistent with congressional intent).

In the context of contracts between an agency and other parties, a court should find that the contracting parties intended to confer enforceable rights on third parties only if the intent to permit third-party enforcement is clear. Under traditional contract principles, a contract confers enforceable rights on third parties only if those parties are intended, rather than incidental, beneficiaries of the contract, and only if "recognition of a right to performance in the beneficiary is appropriate to effectuate the intention of the parties."[8] Restatement (Second) of Contracts § 302(1) (1981) (Restatement).

Thus, even when the contract is intended to benefit a discrete class of parties, the parties must have intended "to confer on a third party an enforceable right concerning which the promisee and the promisor bargained." 13 Samuel Williston & Richard A. Lord, *A*

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[8] Federal common law governs contracts that are entered into by an agency pursuant to a federal statute, see *United States* v. *Seckinger*, 397 U.S. 203, 209-210 (1970), but the Court may use traditional rules of contract law to guide its determination of federal law, as long as those rules are consistent with federal statutes and policies. See *Textile Workers Un.* v. *Lincoln Mills*, 353 U.S. 448, 456-457 (1957).

*Treatise on the Law of Contracts* § 37:8, at 79 (4th ed. 2000). This latter requirement is rigorously enforced in the context of government contracts. See Restatement § 313, cmt. a; 9 John E. Murray, Jr., *Corbin on Contracts* § 45.6, at 92 (rev. ed. 2007) ("The distinction between an intention to benefit a third party and an intention that the third party should have the right to enforce that intention is emphasized where the promisee is a governmental entity."); see also *German Alliance Ins. Co.* v. *Home Water Supply Co.*, 226 U.S. 220, 230-231 (1912).

When government contracts operate as part of a broader statutory and regulatory scheme, the Restatement provides that a court, in assessing the intent of the parties, should not permit third-party enforcement "to the extent that application would contravene the policy of the law authorizing the contract or prescribing remedies for its breach." Restatement § 313(1). Therefore, congressional intent with respect to third-party enforcement of the statutory scheme is also relevant at this stage of the third-party-beneficiary analysis, as is the potential for third-party suits to disrupt an agency's ability to act as a centralized regulator. These considerations in turn bear on the agency's intent in contracting and whether the contract should be construed to confer enforceable third-party rights.

### B. The PPA Does Not Grant Respondent The Right To Enforce Petitioners' Obligations

This Court need not decide whether Section 256b, as it existed at the time the PPA was drafted, permitted HHS to confer third-party beneficiary rights to enforce the manufacturers' obligations. Even if the statutory

scheme is construed not to foreclose HHS from doing so, and even if 340B entities are assumed to be direct beneficiaries of the PPA, there can be no question that the PPA does not manifest any intent to grant 340B entities the right to enforce petitioners' obligations. As discussed above, see pp. 16-17, *supra*, the terms of the PPA upon which respondent relies are in fact incorporations of statutory requirements, rather than independent provisions of the contract. Construing the PPA to confer such enforcement rights would be in considerable tension with Congress's evident intent—confirmed by the amendments to the 340B scheme enacted in the PPACA—to concentrate enforcement authority in the government, whether under the PPACA, the False Claims Act, or otherwise.

1. a. The text of the PPA demonstrates that the parties did not intend to grant covered entities any enforceable contract rights. The PPA confers enforcement authority solely on HHS: the agency may at its discretion invoke the regulatory dispute resolution process in order to ensure that manufacturers comply with their obligations. Pet. App. 174a. When HHS initiates that procedure and finds that the manufacturer has overcharged covered entities, it may require the manufacturer to reimburse covered entities. *Ibid.* That is the primary relief that respondent seeks through its breach-of-contract claim.

Notably, the PPA itself does not provide covered entities with any mechanism to invoke the voluntary dispute resolution procedure. Indeed, the PPA does not explicitly contemplate any claims by covered entities, even as it permits manufacturers to request that HHS adjudicate covered entities' compliance with Section

256b(a)(5). Pet. App. 173a. HHS has accorded covered entities the ability to request dispute resolution if they believe they have been overcharged—but HHS established that right through regulatory guidance, not the PPA. See 61 Fed. Reg. 65,412. HHS thus has never viewed the PPA as governing covered entities' remedies.

The PPA's remedial savings clause confirms this interpretation. That provision states that the agreement's dispute resolution mechanism does not "preclude the *Manufacturer* or the *Secretary* from exercising such other remedies as may be available by law." Pet. App. 175a (emphases added). The absence of any mention of covered entities in this provision demonstrates that HHS, which prepared the PPA, and the manufacturers, which accepted it, did not view the PPA as giving rise to or governing any remedies for covered entities.

b. The industry backdrop against which the PPA was drafted also underscores that covered entities lack enforceable contract rights. Manufacturers generally do not distribute drugs directly to health-care providers; rather, they enter into distribution arrangements with wholesalers, which in turn sell to providers. See *340B Report* 2; David H. Kreling, *The Market for Pharmaceuticals: The Big Picture, in* Handbook of Pharmaceutical Public Policy 48 (Thomas R. Fulda & Albert I. Wertheimer eds., 2007). As a result, health-care providers that purchase pharmaceuticals generally have no direct contractual relationship with manufacturers, and a provider's remedies for overcharges ordinarily would not include a breach-of-contract action directly against the drug manufacturer.

The PPA works within this existing industry practice to govern the prices that manufacturers may charge

covered entities; it does not purport to regulate or alter the business relationships among industry actors. See OIG, HHS, *Deficiencies in the Oversight of the 340B Drug Pricing Program* 5 (Oct. 2005) (*2005 Report*); 58 Fed. Reg. at 27,291. Respondent thus acknowledges that it purchased its drugs from wholesalers, and that it has no contractual privity with petitioners.[9] Pl. Mot. for Joinder, Remand and/or Dismissal 8, 3:05-cv-03740, Docket entry No. 61 (N.D. Cal. Oct. 17, 2005). Absent a third-party beneficiary claim under the PPA, covered entities would ordinarily have no breach-of-contract remedy against manufacturers. Had the parties intended to alter these pre-existing relationships by granting covered entities the right to sue manufacturers directly, they would have made that intent manifest.

2. The Medicaid Act's prohibition on disclosure of manufacturers' pricing information to covered entities further indicates that the parties did not intend to create enforceable rights in covered entities. With certain exceptions, the Medicaid Act bars HHS from disclosing any pricing information in a form that could reveal the "prices charged for drugs by such manufacturer." 42 U.S.C. 1396r-8(b)(3)(D). HHS interprets this provision as prohibiting the agency from disclosing to covered entities the ceiling price that the agency calculates based on AMP and Best Price.[10] See 59 Fed. Reg. 25,110

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[9] Covered entities sometimes contract directly with manufacturers, see *2005 Report* 4, for instance, when they negotiate prices that are lower than the ceiling price.

[10] In 2005, Congress amended the confidentiality requirement to permit HHS to disclose AMP figures on a publicly accessible website. See 42 U.S.C. 1396r-8(b)(3)(D)(v); Deficit Reduction Act, Pub. L. No. 109-171, § 6001, 120 Stat. 55. HHS was enjoined from disclosing these data

(1994); *Oversight Report* 5 & n.11; see also *Beck* v. *PACE Int'l Union*, 551 U.S. 96, 104 (2007) (agency interpretation of statute, expressed in amicus brief, is entitled to deference). As a result, covered entities have no way of determining whether the price that a manufacturer offers them is in fact the correct ceiling price. See *Oversight Report* 5. Indeed, respondent alleged as much in its complaint, stating that because HHS keeps pricing data confidential under Section 1396r-8(b)(3)(D), "[respondent] do[es] not possess and cannot without Court order obtain the information necessary to verify that the prices the Counties pay for prescription drugs are at or below the §340B ceiling price." J.A. 48-49.

As part of the governing statutory framework, the confidentiality requirement is incorporated into the PPA. See *Erika*, 456 U.S. at 211 n.14. The parties cannot have intended to grant 340B entities enforceable rights under the PPA in the face of a statutory provision that bars such entities from obtaining the very information necessary to determine whether their purported rights have been violated.

3. Construing the PPA to confer broad enforcement rights on covered entities also would be inconsistent

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as a result of a district court's finding that certain components of CMS's AMP definition were likely invalid. See *National Ass'n of Chain Drug Stores* v. *HHS*, 631 F. Supp. 2d 17, 18 (D.D.C. 2009). In any event, this exception does not apply to Best Price data, and therefore it does not suggest that the ceiling prices may be disclosed to covered entities.

Going forward, the PPACA will alter the confidentiality framework governing claims by 340B entities. In connection with the new administrative adjudication process, HHS must permit covered entities some discovery of information from manufacturers and third parties. Pub. L. No. 111-148, § 7102(a), 124 Stat. 826.

with Congress's decision to vest authority to enforce the Medicaid Rebate and 340B programs in the government, and would undermine HHS's ability to administer both programs.

The Medicaid Act contains a comprehensive remedial scheme that enables HHS to ensure that manufacturers accurately calculate and report AMP and Best Price—the bases of the 340B ceiling price calculation. HHS may audit and investigate manufacturers' calculations of AMP and Best Price, impose monetary penalties for inaccuracies, and terminate a manufacturer's participation in the Medicaid Rebate Program based on reporting errors or other good cause. 42 U.S.C. 1396r-8(b)(3)(A)-(C) and (4)(B). Beyond administrative enforcement, the government, in coordination with HHS, can pursue False Claims Act (FCA) actions, see 31 U.S.C. 3729 *et seq.*, and common-law fraud, unjust enrichment and similar actions, against manufacturers that evade their reporting obligations under the Medicaid Rebate Program.[11] Cf., *e.g.*, *United States ex rel. Roberts* v. *Aging*

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[11] The government's pursuit of an FCA action reflects its conclusion, in coordination with HHS, that a manufacturer's calculations violate the Medicaid rebate framework, and it is thus consistent with Congress's intent that HHS should have the initial opportunity to determine manufacturers' obligations. The government's initial determination in bringing the suit is of course subject to judicial adjudication, in that whether the government will prevail on its fraud claims in court "ultimately" depends on "judicial interpretation," U.S. Br. in Opp. to Mot. to Dismiss, *United States ex rel. Kieff* v. *Wyeth*, 03-cv-12366, Docket entry No. 141 at 37 (D. Mass. Dec. 11, 2009), with deference to administrative interpretation of relevant statutory and regulatory provisions. This familiar judicial role in enforcement actions brought by the United States, subject to the checks imposed by prosecutorial discretion, in no

*Care Home Health, Inc.*, 474 F. Supp. 2d 810, 820-821 (W.D. La. 2007) (unjust-enrichment claim to enforce Medicare provider's statutory obligations). On the 340B side, in addition to the enforcement measures provided by the PPA and the informal dispute resolution process, HRSA may terminate a manufacturer's participation in the 340B program.[12] 42 U.S.C. 1396r-8(b)(4)(B)(v); see Pet. App. 171a, 174a; 61 Fed. Reg. at 65,411-65,412. Congress's creation of these remedies for various violations by manufacturers of their statutory accurate-reporting and pricing obligations, and its failure to create any private enforcement mechanism for 340B rights, indicates that covered entities may not bypass the scheme of government enforcement by relying on purported contractual rights.

Respondent advances two primary arguments against this conclusion, neither of which is persuasive. First, respondent contends that HHS has previously indicated that, in its view, the 340B enforcement scheme does not place enforcement authority "either preliminarily or exclusively within the agency." Br. in Opp. 26. Respondent relies on HHS's responses to comments

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way suggests that the 340B Program allows for private suits by thousands of covered entities.

[12] Respondent contends that HRSA lacks effective enforcement authority because the termination sanction is too extreme to be a realistic option. Br. in Opp. 28-30. As discussed above, however, the PPACA gives HRSA additional enforcement tools. Respondent's argument also overlooks the fact that the primary conduct of which it complains—petitioners' alleged failure to comply with the accurate-reporting requirements of the Medicaid Rebate Program—can be investigated and remedied by CMS, see 42 U.S.C. 1396r-8(b)(3)(C), or prosecuted under other available civil or criminal statutes.

regarding its informal dispute resolution procedure, in which HHS stated that while "[n]o manufacturer or covered entity is required to avail itself of this process before resorting to other available measures," HHS expected that "parties" would "utilize the process before resorting to other remedies which may be available under applicable principles of law." 61 Fed. Reg. at 65,411-65,412. These statements do not purport to express a view regarding whether covered entities might be able to pursue other remedies for overcharges, and if so, what those remedies might be. Nor does HHS's description of the informal dispute resolution procedure as voluntary and not preclusive of other potential actions speak to whether the *PPA* confers enforceable rights on covered entities, or whether the combined Medicaid Rebate and 340B statutory schemes weigh against so construing the PPA.

Second, respondent contends that HHS's enforcement authority and its exercise of that authority have been inadequate. Respondent relies on government investigations that found that 340B entities had sometimes been overcharged, and recommended improvements in HRSA's oversight practices.[13] See *2005 Report* 10-15; *Oversight Report* 9-10. Respondent's view that HRSA should have more rigorously enforced manufacturer compliance, however, does not alter the fact that Congress centralized enforcement in the government, and that construing the PPA as respondent urges would be inconsistent with that intent.

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[13] HRSA has implemented many improvements in response. See, *e.g.*, *Oversight Report* 9-10, 12.

In any event, in the PPACA Congress confirmed its desire to keep enforcement authority in the government by directing HRSA to create a formal dispute resolution procedure, institute refund and civil penalty systems, and perform audits of manufacturers. § 7102(a), 124 Stat. 823-827. It is notable that, in response to questions about the adequacy of HRSA's enforcement practices in the pre-PPACA system, Congress opted to strengthen and formalize HRSA's enforcement authority, rather than providing for a direct private right of action. See *ibid.* The PPACA thus obviates respondent's enforcement concerns going forward—covered entities may invoke the new adjudicative process to remedy any perceived overcharges—and confirms that the PPA should not be construed to permit respondent to bypass the statutory remedial scheme.

Congress's provision of these extensive administrative procedures in the Medicaid and 340B statutes, and its formalization and enhancement of these procedures in the PPACA, reflect its judgment that HHS, as the administrator of the Medicaid Rebate and 340B programs, is best positioned to determine manufacturers' obligations in the first instance. HHS's comprehensive regulations govern manufacturers' calculation of AMP and Best Price, and when a covered entity alleges, as does respondent, that 340B overcharges are in part the result of inaccurate AMP and Best Price calculations, HHS should have the opportunity to exercise its expert judgment as to the proper application of its regulations. See *Illinois Council*, 529 U.S. at 13.

Permitting covered entities to enforce manufacturers' obligations in individual contract suits would undermine HHS's ability to administer both the Medicaid Re-

bate and the 340B Programs. The interdependent nature of the two programs' requirements means that an adjudication of rights under one program must proceed with an eye towards any implications for the other. In addition, allowing third-party beneficiary claims could result in a flood of litigation by covered entities challenging various aspects of manufacturers' calculations of the AMP, Best Price and ceiling price of numerous drugs. HHS cannot reasonably participate in every suit that might be filed, and so the potential for conflicting obligations imposed by adjudication without the benefit of HHS's participation or expertise is quite high. This result would undermine HHS's own enforcement efforts and the government's fraud actions.[14] Cf. *Buckman Co.* v. *Plaintiff's Legal Comm.*, 531 U.S. 341, 350 (2001) (finding state-law "fraud-on-the-FDA claims" preempted based on the agency's "responsibility to police fraud

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[14] Third-party beneficiary suits by covered entities are thus quite different from suits by States to enforce manufacturers' obligations under the Medicaid Rebate Program. In *In re Pharmaceutical Industry Average Wholesale Price Litigation*, 321 F. Supp. 2d 187 (D. Mass. 2004), for instance, the United States took the position that two States' state-law fraud suit based on Best Price figures was not preempted. As the government explained, the Medicaid Rebate Program, like Medicaid generally, is a "cooperative federal-state program," in which States make their own payments to manufacturers and therefore have "long played a role" in identifying and prosecuting fraud. Gov't Amicus Br. 6-9 & n.5, 01-cv-12257, Docket entry No. 743 (March 18, 2004). Such suits, in which the United States would play a cooperative role, do not present the danger of inconsistent judgments uninformed by HHS's expertise that covered-entity suits would. *Id.* at 16-17.

consistently with the Administration's judgment and objectives").[15]

## CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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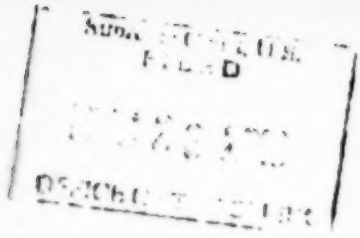
[15] The primary jurisdiction doctrine does not mitigate the concerns raised by allowing third-party beneficiary suits, because referral to HHS would depend on a case-by-case judicial determination, *United States* v. *Western Pac. R.R.*, 352 U.S. 59, 64 (1956), and could interfere with HHS's enforcement priorities.

# AMICUS CURIAE BRIEF



No. 09-1273

In the
Supreme Court of the United States

ASTRA USA, INC., ET AL.,
*Petitioners,*

v.

COUNTY OF SANTA CLARA,
*Respondent.*

On Writ of Certiorari to the
United States Court of Appeals
for the Ninth Circuit

# BRIEF OF AARP AND NATIONAL SENIOR CITIZENS LAW CENTER AS *AMICI CURIAE* IN SUPPORT OF RESPONDENTS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Irma S. Russell, *A Common Tragedy: The Breach of Promises to Benefit the Public Common and the Enforceability Problem*, 11 Tex. Wesleyan L. Rev. 557 (2005) ..... 10

## STATEMENTS OF INTEREST[1]

AARP is a nonpartisan, nonprofit organization dedicated to addressing the needs and interests of people aged fifty and older. AARP has a long history of advocating for access to affordable and quality health and long-term care. To that end, AARP supports efforts to protect state Medicaid funds because strengthening Medicaid is an essential foundation of the nation's health care system. Medicaid is the nation's largest payer for long-term care and is critical in redirecting care from institutions to often more cost-effective home and community-based settings that older persons prefer. Although older and disabled persons make up just one-quarter of Medicaid enrollees, they account for 70 percent of Medicaid spending; and Medicaid provides essential assistance to more than eight million "dual eligible" low-income Medicare beneficiaries who tend to have significant chronic health care needs. In addition, AARP has a strong interest in this case because ensuring that prescription medications are affordable is especially important to older people who have the highest rate of prescription drug use as a result of their higher rate of chronic and serious health conditions.

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represent that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel, nor any other person or entity other than *amici*, its members or its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. All parties have consented to the filing of *amicus* briefs and have filed letters reflecting their blanket consent with the Clerk.

Because prescription drug spending has skyrocketed over the last fifteen years, thereby limiting access to medically necessary medicines for many people, AARP advocates for policies, laws, and other efforts that broaden access to affordable prescription drugs.

The National Senior Citizens Law Center ("NSCLC") is a non-profit organization whose principal mission is to protect the rights of low-income older adults. For more than 35 years, NSCLC has sought to ensure the health and economic security of older persons with limited income and resources, through advocacy, litigation, and the education and counseling of local advocates. NSCLC's *Federal Rights Project* seeks to keep the courts open to justice and works to ensure that people retain the right to enforce basic guarantees to health care, economic security and civil rights. Medicaid is a critical source of health insurance for millions of low-income older persons, and NSCLC has participated as counsel in numerous lawsuits regarding Medicaid. NSCLC is profoundly concerned about the impact that the Court's decision may have on its clients' access to affordable prescription drugs.

## SUMMARY OF THE ARGUMENT

Both federal and state common law provide a cause of action for an intended third-party beneficiary to bring suit for breach of contract. The Restatement (Second) of Contracts encapsulates the principles of common law and recognizes the availability of a contract claim to an intended third-party beneficiary. While the contract in this case

incorporates the requirements of federal law, there is nothing in the underlying statute which divests the courts of jurisdiction to decide contract claims.

Third-party beneficiary claims have widespread acceptance in the jurisprudence of state courts, though states utilize a variety of standards for determining whether a plaintiff meets the requirements for an intended third-party beneficiary. Numerous state courts have allowed third-party claims to proceed to enforce requirements incorporated in contracts between the government and private parties, when these contracts are designed for the intended purpose of benefitting a specific group. The decision regarding third-party beneficiaries in this case should not impede the right of states to develop their own common law of contracts.

## ARGUMENT

### I. IT IS WELL ESTABLISHED THAT THE COMMON LAW PROVIDES A CAUSE OF ACTION TO AN INTENDED THIRD-PARTY BENEFICIARY TO ENFORCE A CONTRACT

Petitioners argue that the absence of a statutory cause of action warrants dismissal of this case. Pet. Op. Brf. 17. Yet, the respondent's right to sue derives from a contract mandated by Congress, and nothing in the applicable statute suggests Congress intended to displace common-law contract remedies for intended third-party beneficiaries. Just as parties to a contract have a common law cause of action to bring suit for breach, it is firmly

established that intended third-party beneficiaries have a common law cause of action to enforce the promises made for their benefit.

The Restatement (Second) of Contracts sets forth "the principles of contract law" for contracts between private parties as well as for contracts entered into by governments. *Mobil Oil Exploration and Producing Se. Inc. v. U.S.*, 530 U.S. 604, 608 (2000). This Court has frequently applied the "common-law rules of contract interpretation" set forth in the Restatement (Second) of Contracts. *Mastrobuono v. Shearson Lehman Hutton, Inc.*, 514 U.S. 52, 62-63 (1995). *See e.g., Stolt-Nielsen S.A. v. AnimalFeeds Int'l Corp.*, 130 S. Ct. 1758, 1775 (2010); *Franconia Assocs v. U.S.*, 536 U.S. 129, 143 (2002). Appellate courts have recognized that the Restatement of Contracts is "an appropriate source of authority in contract cases." *Hansen Bancorp., Inc. v. U.S.*, 367 F.3d 1297, 1308 n.9 (Fed. Cir. 2007). The Restatement "accurately reflects the general common law of the United States." *Canfield v. Security-First Nat. Bank of Los Angeles*, 87 P.2d 840, 845 (Cal. 1939), cited in *Lake Almanor Assocs. L.P. v. Huffman-Broadway Group Inc.*, 178 Cal.App.4th 1194, 1201, n.4 (Cal. App. 1 Dist. 2009) (Restatement is "entitled to great consideration as an argumentative authority").

The Restatement (Second) of Contracts § 302 provides criteria for distinguishing incidental beneficiaries from intended beneficiaries and establishes that an intended third-party beneficiary may enforce the duty contained in a promise in a contract that was intended for his or her benefit.

Restatement § 304. The Federal Circuit noted that, pursuant to the Restatement § 302, "a third-party beneficiary of a contract to which the government is a direct party may assert a claim ... in accordance with the rules applicable to third-party claims." *Flexfab, L.L.C. v. United States*, 424 F.3d 1254 (Fed. Cir. 2005). The *en banc* Supreme Court of Missouri similarly explained, "A third-party beneficiary is one who is not privy to a contract or its consideration but who may nonetheless maintain a cause of action for breach of the contract." *Andres v. Albano*, 853 S.W.2d 936, 942 (Mo. 1993) (en banc). Applying the Restatement § 302, the Supreme Court of Alaska observed that the third-party beneficiary cause of action arises under contract law and does not require a statutory cause of action. *Smallwood v. Cent. Peninsula Gen. Hosp.*, 151 P.3d 319, 324 (Alaska 2006). Thus, both the federal common law and the common law of many states follow the Restatement (Second) and provide intended third-party beneficiaries with a cause of action to remedy a breach of the contract.

The statutory provision that directs the federal government to enter into contracts limiting the price of drugs, 42 U.S.C. § 256b, does not divest federal courts of jurisdiction to hear contract claims. *See Verizon Md. Inc. v. Public Serv. Comm'n*, 535 U.S. 635, 642 (2002). Clearly, the parties to such a contract could sue each other for breach of contract, since there is nothing in the underlying statute precluding contract law remedies for the parties. Likewise, the statute does not divest federal courts of jurisdiction to hear common law contract claims brought by third-party beneficiaries.

Moreover, § 256b incorporates certain pricing standards from the Medicaid statute. The Medicaid statute does not contain a comprehensive remedial scheme that would preclude review, because this statute does not provide any remedies for private parties, such as respondent, under the circumstances of the instant case. This Court has noted that statutes may preclude other remedies when they provide a detailed remedial scheme for private parties. *Blessing v. Freestone*, 520 U.S. 329, 347 (1997). Even when beneficiaries have administrative remedies under the Medicaid statute, this Court has held that the statute does not contain a comprehensive remedial scheme that would preclude claims under 42 U.S.C. § 1983 for Medicaid recipients who are clearly the intended beneficiaries of the Medicaid law. *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 521-22 (1990). *See also Wright v. City of Roanoke Redev. & Hous. Auth.*, 479 U.S. 418, 427-8 (1987); *Rosado v. Wyman*, 397 U.S. 397, 406 (1970). There is no logical basis for finding a comprehensive remedial scheme in the Medicaid law for precluding contract claims, since the Court has already held that the statute does not preclude § 1983 claims. Moreover, the absence of any administrative remedies for respondent demonstrates that there is a not a comprehensive remedial scheme that would preclude ordinary contract law remedies, including third-party beneficiary claims.

## II. STATE CONTRACT LAW PROVIDES REMEDIES TO INTENDED THIRD-PARTY BENEFICIARIES AND STATE LAW REMEDIES SHOULD NOT BE TRAMPLED UPON

State courts and legislatures have addressed the availability of a cause of action for breach of contract for an intended third-party beneficiary in a myriad of ways. Some state legislatures have enacted statutes codifying the common law relief for intended third-party beneficiaries. In other states, the doctrine has been established entirely through case law. While many states have adopted the standards identified in the Restatement (Second) of Contracts, a few states have imposed more stringent criteria for a cause of action for third-party beneficiary claims. The Court's holding in this case should preserve the freedom of states to fashion contract law in accordance with divergent state preferences.

### A. While State Standards Vary, State Courts Permit Claims by Intended Third-Party Beneficiaries

The Restatement (Second)'s formulation of the common law regarding intended third-party beneficiaries in § 302 has been adopted by the highest courts of numerous states. *See, e.g., Smallwood*, 151 P.3d at 324 ; *Rumford v. Valley Pest Control, Inc.*, 629 So.2d 623, 631 (Ala. 1993); *Scarpitti v. Weborg*, 530 Pa. 366, 370-71 (Pa. 1992); *Hill v. Sonitrol of Sw. Oh., Inc.*, 521 N.E.2d 780, 784 (Ohio 1988); *Fourth Ocean Putnam Corp. v.*

*Interstate Wrecking Co., Inc.*, 485 N.E.2d 208, 212 (NY 1985); *Cretex Co., Inc. v. Constr. Leaders, Inc.*, 342 N.W.2d 135, 139 (Minn. 1984); *Midwest Dredging Co. v. McAninch Corp.*, 424 N.W.2d 216, 224 (Iowa 1988). Thus, numerous state courts recognize the right of third-party beneficiaries to sue to enforce a breach of contract.

Several states have enacted statutes that specify the right of intended third-party beneficiaries to bring an action under state contract law. For example, Georgia's statutory code provides: "The beneficiary of a contract made between other parties for his benefit may maintain an action against the promisor on the contract." Ga. Code. Ann. § 9-2-20. *See also* Mich. Comp. Laws § 600.1405 (1996); Cal. Civ. Code § 1559. Similarly, Louisiana's civil code states that a third-party beneficiary has "the right to demand performance from the promisor." LSA-CC Art. 1981. A comment to the Louisiana code notes that the "direct right of the beneficiary to demand performance has been consistently recognized by the Louisiana courts" since a case decided in 1818. In contrast, West Virginia's civil code drastically limits the availability of relief for third-party beneficiaries, specifying that a party may sue as a third-party beneficiary only if the promise in the contract has been made for his "sole benefit." W. Va. Code, § 55-8-12. *See E. Steel Constr. Inc. v. City of Salem*, 549 S.E.2d 266 (W. Va. 2001).

State courts in Illinois and Texas apply a strong presumption against third-party beneficiary enforcement of the contract. *Shank v. H.C. Fields*, 869 N.E.2d 261, 268 (Ill. App. 2007); *Ortega v. City*

*Nat. Bank*, 97 S.W.3d 765, 773 (Tex. App. 2003). Nevertheless, even in those states, third-party claims have prevailed when supported by evidence of the clear intent of the contract to confer a benefit on the third-party. *Stine v. Stewart*, 80 S.W.3d 586, 590 (Tex. 2002) (per curium); *Bates & Rogers Constr. Co. v. Greely & Hansen*, 486 N.E.2d 902, 906 (Ill. 1985).

While utilizing not quite as stringent a standard as Illinois and Texas, the Supreme Courts of Arkansas and Kansas have applied a presumption that parties contract only for their own benefit. *Elsner v. Farmers Ins. Group*, 220 S.W.3d 633, 635 (Ark. 2005); *State ex rel. Stovall v. Reliance Ins. Co.*, 107 P.3d 1219, 1231 (Kan. 2005). These courts still permit third-party claims to proceed when there is substantial evidence of a clear intent to benefit a third-party. *Fasse v. Lower Heating & Air Conditioning, Inc.*, 736 P.2d 930, 934 (Kan. 1987); *Howell v. Worth James Const. Co*, 535 S.W.2d 826, 829 (Ark. 1976).

In sum, there is a rich body of state doctrine permitting third-party beneficiary claims under state contract law. Petitioners' argument that a contract claim by a third-party beneficiary cannot proceed without a statutory cause of action ignores the acceptance of common law third-party beneficiary claims by numerous state courts.

### B. Courts Applying State Law Have Permitted Intended Third-Party Beneficiary Claims Arising From Government Contracts Involving Health Care and Social Services

In recent years, for-profit firms have played a greater role in the delivery of health care and social services "as economic conditions make social welfare delivery increasingly attractive to for-profit firms." Jody Freeman, *The Private Role in Public Governance*, 75 N.Y.U. L. Rev. 543, 595 (2000). Due to the "inadequacy of traditional accountability mechanisms" when for-profit firms administer public programs, "enforceable legal contracts emerge as a potentially crucial tool." *Id.* at 598. Third-party beneficiary claims can serve "to protect the public interest and to supplement the efforts of regulatory agencies." Irma S. Russell, *A Common Tragedy: The Breach of Promises to Benefit the Public Common and the Enforceability Problem*, 11 Tex. Wesleyan L. Rev. 557, 561 (2005).

State courts and federal courts applying state law have permitted third-party beneficiary claims against private parties to enforce contracts enacted to implement Medicaid requirements, provide services to prisoners, and supply housing. The decision in this case should not encroach upon the power of states to permit claims by intended third-party beneficiaries under state law.

In *Smallwood*, 151 P.3d at 319, the hospital admitted that it automatically billed Medicaid recipients for charges rejected by the state, a

practice known as "balance billing." This practice was in direct violation of federal and state Medicaid law, encapsulated in the hospital's agreement with the state, which prohibit providers from billing Medicaid patients for amounts beyond authorized copayments. The Alaska Supreme Court held that the plaintiff could pursue injunctive and declaratory relief as a third-party beneficiary of the contract between the hospital and the state. Following the Restatement § 302, the court found that "the state intended that Medicaid recipients like Smallwood benefit from providers' promises not to balance bill." *Id.* at 325. The court therefore permitted the plaintiff to enforce the provider agreement as a third-party beneficiary. The court also held that the possibility of enforcement by the government did not foreclose the plaintiff's claim because he had no assurance of enforcement in *his* case, and he was not entitled to a state administrative hearing regarding the hospital's improper billing. *Id.* at 326-27.

In another case involving a violation of Medicaid law, a nursing home refused to readmit a paraplegic resident after he went to the hospital for treatment of an ulcer. *Smith v. Chattanooga Med. Investors, Inc.*, 62 S.W.3d 178, 181 (Tenn. Ct. App. 2001). The contract between the state and the nursing home required the nursing home to comply with federal and state rules, including rules governing the readmission of a patient after a transfer to a hospital. *Id.* at 187. The state appellate court noted that the intent of the contract was specifically to benefit Medicaid-eligible residents who receive care at that facility, and not to benefit the general public. *Id.* at 185-86. The court

therefore concluded that the plaintiff could bring suit as a third-party beneficiary to enforce the contract between the state and nursing home. *Id.*

In two suits in federal court against nursing homes alleging the failure to provide the level of care agreed to in contracts between the states and nursing homes, district courts permitted third-party beneficiary claims to proceed. *Brown v. Sun Healthcare Group Inc.*, 476 F. Supp. 2d 848, 853 (E.D. Tenn. 2007) (applying Tennessee law); *Brogdon v. Nat'l Healthcare Corp.*, 103 F. Supp. 2d 1322 (N.D. Ga. 2000) (applying Georgia law). In both cases, the courts found that the Medicaid statute did not provide an implied private right of action to Medicaid recipients. *Brown*, 476 F.Supp.2d at 851; *Brogden*, 103 F.Supp.2d at 1330. Nevertheless, under both Tennessee and Georgia law, Medicaid recipients could pursue contract claims against the nursing facilities as intended third-party beneficiaries. *Brown*, 476 F.Supp.2d at 853; *Brogden*, 103 F.Supp.2d at 1334; *accord Solter v. Health Partners of Philadelphia Inc.*, 215 F. Supp. 2d 533, 539 n.8 (E.D. Pa. 2002) (no private right of action under Medicaid Act but third-party beneficiary claim under state law available to enforce contract between managed care organization and state regarding provision of medically necessary care). The courts both found that Congress did not intend to "displace state law in this area." *Brown*, 476 F.Supp.2d at 853; *Brogden*, 103 F.Supp.2d at 1334. In *Brogdon*, the court refused to dismiss the case based on the doctrine of primary jurisdiction, noting that "Medicaid provides no scheme for

administrative enforcement of Plaintiffs' claims." 103 F.Supp.2d at 1329.

The Supreme Court of Virginia similarly allowed a prisoner who alleged that he was injured by inadequate medical care to enforce a contract between the state and a private provider of medical services for prisoners. *Ogunde v. Prison Health Serv. Inc.*, 645 S.E.2d 520 (Va. 2007). The contract's stated purpose was to "provide cost effective, quality inmate health care services for up to . . . inmates," and it defined the scope of services to be provided to the prisoners. *Id.* at 525-26. The court found that the contract rendered a direct benefit to the inmates, which was clearly the intention of the contracting parties, and therefore reversed the dismissal of the prisoner's third-party beneficiary contract claim. *Id.* *Accord Rathke v. Corr. Corp. of Am.*, 153 P.3d 303 (Alaska 2007) (prisoners are third-party beneficiaries of contract between state and private prison operator). *See also Miller v. Corr. Corp. of Am.*, 239 Fed. App'x. 396 (9th Cir. 2007) (applying Alaska law and following *Rathke*).

The Supreme Judicial Court of Massachusetts held that, under Massachusetts law, tenants can pursue contract claims as third-party beneficiaries of housing contracts enacted pursuant to federal housing programs, in cases involving landlords' failure to correct lead paint hazards. *Campbell v. Boston Hous. Auth.*, 823 N.E.2d 363 (Mass. 2005); *Ayala v. Boston Housing Authority*, 536 N.E.2d 1082 (Mass. 1989). Nevertheless, in both housing and prisoner cases, third-party beneficiary claims have been denied when the contracts included

exclusionary clauses disclaiming any intent to confer rights to performance on third-parties. *Jama v. U.S. Immigration and Naturalization Serv.*, 334 F. Supp.2d 662, 687 (D.N.J. 2004) (prisoner); *Anderson v. D.C. Hous. Auth.*, 923 A.2d 853, 863 n. 20 (D.C. 2007) (housing); *Dewakuku v. Cuomo*, 271 F.3d 1031 (Fed. Cir. 2001) (housing).

Petitioner's argument that no third-party beneficiary claims should be permitted without a federal statutory cause of action would undermine state law cases permitting recipients of federal benefits to enforce contracts against private providers for violations including improper billing, unlawful eviction from nursing homes, inadequate medical care, and hazardous lead paint. State courts and legislatures should be free to develop state law to protect their residents from such harms.

## CONCLUSION

For the reasons stated, *amici* urge the Court to affirm the decision below.

December 20, 2010

Respectfully Submitted,

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# AMICUS CURIAE BRIEF

Supreme Court, U.S.
FILED
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No. 09-1273

# In The Supreme Court of the United States

ASTRA USA, INC., *ET AL.*,

PETITIONERS,

v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

RESPONDENT.

**On Writ of *Certiorari* to the U.S. Court of Appeals for the Ninth Circuit**

## BRIEF FOR APA WATCH AS *AMICUS CURIAE* SUPPORTING PETITIONERS

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## QUESTION PRESENTED

Section 340B of the Public Health Service Act, 42 U.S.C. §256b, imposes ceilings on the prices that drug manufacturers may charge for prescription medicines sold to specified health care facilities and entities, known as "340B entities." Section 340B implements the ceiling prices by requiring the Secretary of Health and Human Services to enter into contracts setting forth the Act's pricing restrictions, and drug manufacturers are required to enter into those contracts as a condition of participation in Medicaid. 42 U.S.C. §§1396b(i)(10), 1396r-8(a)(1), (a)(5).

In the decision below, the Ninth Circuit held that covered 340B entities have a private right of action under "federal common law" to enforce the Act's pricing requirements, even though the Act itself contains no express or implied private right of action. The Ninth Circuit held that a plaintiff may pursue a federal common-law claim as a third-party beneficiary of a contract that embodies statutory requirements.

The question presented is whether, in the absence of a private right of action to enforce a statute, federal courts have the federal common-law authority to confer a private right of action on non-parties to the contract simply because the statutory requirement sought to be enforced is embodied in the contract.

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No. 09-1273

# In The Supreme Court of the United States

ASTRA USA, INC., *ET AL.*,

PETITIONERS,

v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

RESPONDENT.

**On Writ of *Certiorari* to the U.S. Court of Appeals for the Ninth Circuit**

## INTEREST OF *AMICUS CURIAE*[1]

*Amicus curiae* APA Watch is a nonprofit membership corporation headquartered in McLean, Virginia. APA Watch has participated as *amicus curiae* before this Court and the Courts of Appeals on third-party enforcement and justiciability issues.

[1] This *amicus* brief is filed with written consent of all parties; the written letters of consent from petitioners and respondent have been lodged with the Clerk of the Court. Pursuant to Rule 37.6, counsel for *amicus curiae* authored this brief and no counsel for a party authored this brief in whole or in part, nor did any person or entity other than the *amicus* and its counsel make a monetary contribution to the preparation or submission of this brief.

*See, e.g., Stormans Inc. v. Seleky*, No. 07-36039 (9th Cir.) (third-party justiciability); *Envtl. Defense v. Duke Energy Corp.*, No. 05-848 (U.S.) (third-party enforcement). Although the third-party enforcement here does not directly affect APA Watch members, second-guessing agency enforcement and disrupting the contract parties' expectations present an issue of fairness on which APA Watch seeks to comment. Moreover, because the litigants have not briefed the plaintiff's standing, APA Watch's perspective on third-party justiciability could aid the Court on a jurisdictional issue antecedent to the parties' merits arguments. For these reasons, APA Watch respectfully files this *amicus* brief.

## FACTUAL AND LEGAL BACKGROUND

In this action, respondent Santa Clara County, California ("Santa Clara") seeks damages from petitioners Astra USA, Inc., AstraZeneca Pharmaceuticals LP, Aventis Pharmaceuticals Inc., Bayer Corp., Bristol-Myers Squibb Co., Pfizer Inc., Merck & Co., Inc. (f/d/b/a Schering-Plough Corp.), SmithKline Beecham Corp. (d/b/a GlaxoSmithKline), TAP Pharmaceutical Products Inc. (n/k/a Takeda Pharmaceuticals North America, Inc.), Wyeth, Inc., Wyeth Pharmaceuticals, Inc., Zeneca Inc., and ZLB Behring LLC (collectively, the "Manufacturers") under standard Pharmaceutical Pricing Agreement ("PPA") contracts that the Manufacturers enter with the federal Department of Health & Human Services ("HHS"). This section sets forth the factual and legal background relevant to the proceeding in this Court.

### Procedural Background

Santa Clara sued the Manufacturers on a variety of federal- and state-law theories, initially in state court but subsequently removed to the U.S.

District Court for the North District of California. The District Court dismissed under FED. R. CIV. P. 12(b)(6) for failure to state a claim on which relief could be granted. Applying the federal common law of contracts, the U.S. Court of Appeals for the Ninth Circuit reversed with respect to Santa Clara's claim to enforce the PPA's provisions for discounted drug prices as an intended direct beneficiary of the PPAs. Although the complaint sought relief under several legal theories, this appeal concerns only the right to sue under the PPA as a third-party beneficiary.

**Statement of Facts**

Although not material to this *amicus* brief, the facts are the allegations set forth in Santa Clara's complaint. J.A. 28-66. Although not a fact *per se,* the complaint also makes clear the legal theory that Santa Clara "and all similarly situated counties ... are the intended beneficiaries" of the PPA. Compl. ¶44, J.A. at 45. The only relevant fact are (1) the PPA's express terms, and (2) that HHS has not invoked PPA ¶IV(c)'s dispute-resolution provisions with respect to the discounts that the Manufacturers allegedly have withheld.

**Medicaid Drug Rebate Program**

Medicaid "impose[s] a general requirement that, in order to qualify for Medicaid payments, drug companies must enter into agreements ... with [HHS] ... to provide rebates on their Medicaid sales of outpatient prescription drugs." *Pharm. Research & Mfrs. of Am. v. Walsh,* 538 U.S. 644, 652 (2003). Having rebate agreements in effect pursuant to §1396r-8 is a condition of Manufacturers' participating in Medicaid. 42 U.S.C. §1396b(i)(10), (a)(1), (a)(5). Medicaid provides various means for HHS to enforce the requirement that Manufacturers

provide the required rebates, 42 U.S.C. §§1396r-8(b)(3)(B), 1396r-8(b)(3)(C)(i)-(ii), 1396r-8(b)(4)(B)(i), but does not include a private cause of action.

**§340B Drug Ceiling Price Program**

Section 340B of the Public Health Service Act of 1992, 42 U.S.C. §256b (hereinafter, "§340B"), requires Manufacturers participating in Medicaid to offer discounted drug prices to qualifying clinics and other healthcare facilities – known as "340B entities" or "safety net providers" – that receive federal funds. 42 U.S.C. §256b(a)(4). The §340B program links to the Medicaid rebate program, 42 U.S.C. §§256b(a)(1), 1396r-8(a)(1), (a)(5), which HHS implements through its standard PPA contract. Pet. App. 165a. Like the larger Medicaid rebate program, the §340B program does not include a private cause of action.

**Pharmaceutical Pricing Agreements**

As relevant to this litigation, the standard HHS PPA contract is set forth in the Appendix to the Manufacturers' Petition for *Certiorari* at Pet. App. 165a-181a. This standard PPA provides five provisions relevant to this litigation:

1. Paragraph IV(c) provides a dispute-resolution provision that is the only contractual vehicle under which the Manufacturers must reimburse discounts to covered entities:

> If [HHS] believes that the Manufacturer has not complied with the provisions of the Agreement, or has refused to submit reports, or has submitted false information pursuant to the Agreement, the Secretary, at his discretion, may initiate the informal dispute resolution process. If so found, the Secretary may require the Manufacturer to reimburse

> the entity for discounts withheld and can also terminate the Agreement.

PPA ¶IV(c), Pet. App. 174a. Significantly, this refund provision expressly provides discretion to HHS and does not discuss or contemplate enforcement directly by covered entities such as Santa Clara.

2. Paragraph IV(e) provides that "[n]othing in [Paragraph IV] shall preclude the Manufacturer or [HHS] from exercising such other remedies as may be available by law." PPA ¶IV(e), Pet. App. 175a.

3. Paragraph VI(c) provides that "[t]he Secretary may terminate the Agreement for a violation of the Agreement or other good cause upon 60 days prior written notice to the Manufacturer of the existence of such violation or other good cause" and that "[d]isputes arising under a contract between a Manufacturer and a covered entity should be resolved according to the terms of that contract." PPA ¶VI(c), Pet. App. 177a. Paragraph VI(c) further requires HHS to provide terminated Manufacturers the opportunity to participate in the dispute-resolution process concerning their termination. *Id.*

4. Paragraph VII(f) provides that "[n]othing in the [PPA] shall be construed as a waiver or relinquishment of any legal rights of the Manufacturer or [HHS] under the Constitution, the Act, or Federal laws, or State laws." PPA ¶VII(f), Pet. App. 180a.

5. Paragraph VII(g) provides that the PPA "shall be construed in accordance with Federal common law" and that "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." PPA ¶VII(g), Pet. App. 180a.

As set forth in more detail in the Argument, these contractual provisions, taken together, provide the exclusive mechanism *under this contract* for requiring the Manufacturers to reimburse covered entities such as Santa Clara, PPA ¶IV(c),[2] require resolution of any disputes between Manufacturers and entities like Santa Clara be resolved under the contract between the entity and the Manufacturer, PPA ¶VI(c), and require that any ambiguities be resolved in the manner that best effectuates the statutory scheme. PPA ¶VII(g). As indicated, that statutory scheme does not contemplate private enforcement by covered entities such as Santa Clara.

**Federal Common Law**

"This Court has consistently held that federal law governs questions involving the rights of the United States arising under nationwide federal programs." *U.S. v. Kimbell Foods, Inc.*, 440 U.S. 715, 726 (1979). Thus, "[f]ederal law typically controls when the Federal Government is a party to a suit involving its rights or obligations under a contract." *Boyle v. United Tech. Corp.*, 487 U.S. 500, 519 (1988); *cf. Empire Healthchoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 691 (2006) ("Court has made clear that uniform federal law need not be applied to all questions in federal government litigation, even in cases involving government contracts") (internal quotations omitted). For *private enforcement* of a

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[2] Although the PPA's dispute-resolution provision does not prevent HHS from enforcing the Manufacturers' statutory obligations via other means, PPA ¶IV(e), Pet. App. 175a, the other means are irrelevant to this litigation, which concerns only enforcement via the PPA itself.

federal contract or program, however, a uniform federal rule of decision is not required if the claim "will have *no direct effect upon the United States or its Treasury.*" *Boyle*, 487 U.S. at 520 (*quoting Miree v. DeKalb County*, 433 U.S. 25, 29 (1977)) (emphasis in *Boyle*). While this Court typically applies federal common law to litigation involving the federal government, it does not necessarily do so for private enforcement of the same federal provisions.

Here, the contracting parties themselves – including a federal agency – have adopted a contract that expressly invokes the federal common law. While that could resolve the issue, it need not: "[c]ontroversies directly affecting the operations of federal programs, although governed by federal law, do not inevitably require resort to uniform federal rules." *Kimbell Foods*, 440 U.S. at 727-28. This Court could adopt a federal rule of decision that looks to state law: "when there is little need for a nationally uniform body of law, state law may be incorporated as the federal rule of decision." *Kimbell Foods*, 440 U.S. at 728. Indeed, "[t]he prudent course ... is often to adopt the readymade body of state law as the federal rule of decision until Congress strikes a different accommodation." *McVeigh*, 547 U.S. at 691-92 (internal quotation omitted). Notwithstanding that the contracting parties elected the federal common law, the federal rule of decision nonetheless could be "*See the state rule.*"

Finally, "federal programs that by their nature are and must be uniform in character throughout the Nation necessitate formulation of controlling federal rules." *Kimbell Foods*, 440 U.S. at 728 (*citing United States v. Yazell*, 382 U.S. 341, 354 (1966)) (interior quotations omitted). "[A]bsent some congressional

authorization to formulate substantive rules of decision, federal common law exists only in such narrow areas as those concerned with the rights and obligations of the United States, interstate and international disputes implicating conflicting rights of States or our relations with foreign nations, and admiralty cases." *Texas Industries, Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 641 (1981) (footnotes omitted). Generally, therefore, this Court has discretion "[w]hether to adopt state law or to fashion a nationwide federal rule," *Kimbell Foods,* 440 U.S. at 728, based on "a variety of considerations ... relevant to the nature of the specific governmental interests and to the effects upon them of applying state law." *U.S. v. Standard Oil Co.,* 332 U.S. 301, 310 (1947). In sum, this Court makes a case-by-case determination on the need for uniform federal rules, based on the totality of the circumstances.

In light of the highly technical nature of both the PPA and the underlying statutes and of the national scope of this litigation through Santa Clara's purporting to represent all similarly situated entities, *amicus* APA Watch respectfully submits that this Court should adopt uniform federal rules of decision. As it happens, however, the rules would be the same under California or federal law.

## SUMMARY OF ARGUMENT

As signaled by the preceding subsection, this case calls upon this Court to adopt a rule of decision under the federal common law. While the parties focus on the availability of a third-party cause of action under the federal common law, *amicus* APA Watch respectfully submits that this Court first must adopt a federal rule of decision for third-party beneficiaries' standing to enforce contracts.

The standing inquiry assumes *arguendo* the plaintiff's merits views (here, that the federal common law provides a cause of action for third-party beneficiaries to enforce the PPA) and then asks whether the plaintiff meets the constitutional and prudential tests for standing. Because it is integral to federal jurisdiction, the standing inquiry comes first. If Santa Clara lacks standing, the case must be dismissed for lack of jurisdiction under FED. R. CIV. P. 12(b)(1), without reaching the lack of a cause of action under FED. R. CIV. P. 12(b)(6).

Notwithstanding that this Court must assume Santa Clara's non-frivolous merits views to evaluate jurisdiction, Section I, *infra*, argues that Santa Clara lacks standing to enforce the PPA as a third-party beneficiary because *even the United States* could not enforce the PPA under contract law, without first invoking the PPA's dispute-resolution provisions. What the promisee lacks a vested right to enforce directly, a third-party beneficiary lacks a cognizable right to enforce indirectly, regardless of whether that third party could enforce the contract after the right vests for the promisee.

If – contrary to the argument in Section I, *infra* – Santa Clara survives the standing analysis, this Court nonetheless should hold that Santa Clara lacks a cause of action to enforce the PPA for the two reasons set out in Section II, *infra*. First, as the Manufacturers argue, the relevant statutes do not create a cause of action, and HHS lacks authority to create a cause of action. *See* Manufacturers' Br. at 18-21. This first reason would constitute a bright-line rule of federal common law. Second, the PPA expressly provides that it "shall be interpreted in the manner [that] best effectuates the statutory scheme,"

PPA ¶VII(g), Pet. App. 180a, and expressly directs enforcement between the Manufacturers and covered entities such as Santa Clara to proceed under the contract between those parties, PPA ¶VI(c), Pet. App. 177a, thereby disavowing an intent that such third parties enforce the PPA under the PPA. Even if this Court avoids a bright-line rule against common-law enforcement by third-party beneficiaries lacking a statutory cause of action, this Court should interpret *this contract* to prohibit that intrusion into the statutory scheme.

## ARGUMENT

Although this Court's "normal role is to interpret law created by others and not to prescribe what [the law] shall be," *Danforth v. Minnesota*, 552 U.S. 264, 290 (2008) (internal quotation omitted), "this Court has ultimate authority to determine and declare" the federal common law. *Taylor v. Sturgell*, 553 U.S. 880, 891 (2008). Here, federal law obviously applies – under Article III for jurisdiction and under the PPA's express terms for the merits – but "[t]he more difficult task ... is giving content to this federal rule." *Kimbell Foods*, 440 U.S. at 727. However this Court gives content to the federal rules of decision for standing and for causes of action, *amicus* APA Watch respectfully submits that this litigation must be dismissed. Santa Clara has no cognizable right, much less a right of action, under the PPAs.

### I. SANTA CLARA LACKS STANDING TO BRING ITS COMMON-LAW CLAIM

Article III limits federal courts to "cases" and "controversies," U.S. CONST. art. III, §2, which requires an actual or imminent "injury in fact" to a cognizable interest. *Lujan v. Defenders of Wildlife*,

504 U.S. 555, 560 (1992). Specifically, constitutional standing presents a tripartite test: "an invasion of a *legally protected interest*" of the plaintiff, caused by the defendants, and redressable by a court. *Defenders of Wildlife*, 504 U.S. at 560-62 (emphasis added). Although Santa Clara's injury arguably results from the United States' discretionary non-enforcement, *amicus* APA Watch assumes *arguendo* that Santa Clara could make out a case for causation and redressability. Santa Clara's problem is more basic. Third-party beneficiaries lack cognizable rights to enforce contractual provisions that the promisee itself could not enforce under the contract.[3]

### A. The Manufacturers Cannot Waive Santa Clara's Lack of Standing

Although the Manufacturers have not contested standing, litigants cannot confer federal jurisdiction by consent or waiver: "no action of the parties can confer subject-matter jurisdiction upon a federal court." *Insurance Corp. of Ireland v. Compagnie des Bauxites de Guinee*, 456 U.S. 694, 702 (1982); *FW/PBS, Inc. v. City of Dallas*, 493 U.S. 215, 231 (1990); *Steel Co. v. Citizens for a Better Env't*, 523 U.S. 83, 95 (1998). To the contrary, because it goes to the Article III "power of the court to entertain the suit," standing "is *the threshold question* in every federal case." *Warth v. Seldin*, 422 U.S. 490, 499 (1975) (emphasis added). "'Without jurisdiction the court cannot proceed at all in any

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[3] Although the PPA does not preclude HHS from enforcing the statutes via other means, *see* note 2, *supra*, this litigation concerns only enforcement of the PPA *as a contract*.

cause. Jurisdiction is power to declare the law, and when it ceases to exist, the only function remaining to the court is that of announcing the fact and dismissing the cause.'" *Steel Co.*, 523 U.S. at 94 (*quoting Ex parte McCardle*, 74 U.S. (7 Wall.) 506, 514 (1868)). Consequently, Santa Clara's standing is antecedent to the cause-of-action question on which the parties join. *Steel Co.*, 523 U.S. at 89-90:

> *It is firmly established in our cases that the absence of a valid ... cause of action does not implicate subject-matter jurisdiction,* i.e., *the courts' statutory or constitutional* power *to adjudicate the case.*

*Id.* at 89 (emphasis in original); *Northwest Airlines, Inc. v. County of Kent*, 510 U.S. 355, 365 (1994) ("[t]he question whether a federal statute creates a claim for relief is not jurisdictional"). Under its precedents – and its constitutional jurisdiction – this Court must evaluate standing before the cause-of-action issue addressed in Section II, *infra*. If Santa Clara lacks standing, that ends the inquiry.

### B. Santa Clara Must Establish its Own Standing to Pursue this Litigation

It is, of course, "axiomatic" that a "litigant first must clearly demonstrate that [it] has suffered an injury in fact in order to assert Article III standing to sue." *Wyoming v. Oklahoma*, 502 U.S. 437, 465 (1992) (interior quotations omitted). Because plaintiffs bear the burden of establishing their standing, federal courts "presume that [they] lack jurisdiction unless the contrary appears affirmatively from the record." *Renne v. Geary*, 501 U.S. 312, 316 (1991). As explained in the next section, Santa Clara lacks standing under the PPA.

Significantly, Santa Clara lacks standing to litigate the United States' injuries. A plaintiff can assert the rights of absent third parties only if the plaintiff itself has constitutional standing, the plaintiff and the absent third parties have a "close" relationship, and a sufficient "hindrance" keeps the absent third party from protecting its own interests. *Kowalski v. Tesmer*, 543 U.S. 125, 128-30 (2004) (*citing Powers v. Ohio*, 499 U.S. 400, 411 (1991)). Here, Santa Clara fails all three prongs: (1) it lacks standing in its own right, (2) it lacks the requisite close relationship with the federal government, and (3) nothing hinders HHS from proceeding against the Manufacturer if Santa Clara is correct on the merits.

Analogously, Santa Clara cannot rely on other counties or similarly situated entities to establish Santa Clara's standing, notwithstanding that Santa Clara sues in a representative capacity: "if none of the named plaintiffs purporting to represent a class establishes the requisite of a case or controversy with the defendants, none may seek relief on behalf of [itself] or any other member of the class." *O'Shea v. Littleton*, 414 U.S. 488, 494 (1974). For Santa Clara to pursue this litigation, therefore, Santa Clara must establish its own standing.

### C. Third-Party Beneficiaries Lack Standing to Enforce Contracts that Have Not Vested in the Promisee

At the outset, only *intended* beneficiaries have standing to enforce an agreement. *Karo v. San Diego Symphony Orchestra Ass'n*, 762 F.2d 819, 821-22 (9th Cir. 1985); *Garcia v. Truck Insurance Exchange*, 36 Cal.3d 426, 436-37 (1984). Those who are not intended beneficiaries are mere interlopers who lack standing to sue to enforce other parties' contract.

*More v. Churchill*, 155 Cal. 368, 369-70 (1909). But even intended third-party beneficiaries "generally have no greater rights in a contract than does the promise[e]." *United Steelworkers of Am. v. Rawson*, 495 U.S. 362, 375 (1990), which links the third-party beneficiaries' rights to the same conditions as the promisee's rights. RESTATEMENT (SECOND) OF CONTRACTS §304 comment b. To the extent that Santa Clara depends on the Manufacturers' PPA obligations to HHS, the rights of Santa Clara are subject to the same conditions precedent as the rights of HHS. *What HHS could not do directly as the promisee, Santa Clara cannot do indirectly as a third-party beneficiary.*

Under *Miree v. DeKalb County*, 433 U.S. 25, 28 (1977), federal courts can look to state law for third-party beneficiaries' standing to enforce federal obligations. California follows the RESTATEMENT (SECOND) OF CONTRACTS, *Martinez v. Socoma Companies, Inc.*, 11 Cal.3d 394, 401-02, 404-05 (1974) (citing RESTATEMENT OF CONTRACTS and then-tentative drafts of the RESTATEMENT (SECOND) OF CONTRACTS); *Outdoor Services, Inc. v. Pabagold, Inc.*, 185 Cal.App.3d 676, 683-84 (Cal. App. 1986) (citing RESTATEMENT (SECOND) OF CONTRACTS), as do most other states. *See, e.g., Guy v. Leiderbach*, 501 Pa. 47, 459 A.2d 744, 750-52 (Pa. 1983); *Joseph v. Hospital Service Dist. No. 2*, 939 So.2d 1206, 1213 (La. 2006).

An intended beneficiary must assert a vested right, *Karo*, 762 F.2d at 822 ("he must be seeking to enforce a right that is personal to him and vested in him at the time of the suit"), without which "[h]e does not have standing to sue as a third party beneficiary because he had no vested rights." *Karo*, at 824. A "vested right" is one "not subject to a

condition precedent." *In re Marriage of Bouquet,* 16 Cal.3d 583, 591 n.7 (1976); *Skookum Oil Co. v. Thomas,* 162 Cal. 539, 545 (1912) ("[n]either will equity relieve such [party] who ... has not fulfilled conditions precedent to the vesting of his right of action"); *Knudson v. City of Ellensburg,* 832 F.2d 1142, 1147 (9th Cir. 1987). Given that HHS could not have brought this action *under contract law* without completing the PPA dispute-resolution prerequisites, PPA ¶IV(c), Pet. App. 174a, neither HHS nor the Manufacturers intended third-party beneficiaries to enforce the PPA without satisfying the PPA's prerequisites.[4] Under the circumstances, Santa Clara lacks third-party standing to enforce the PPAs.

Unmet conditions precedent can affect both standing under Rule 12(b)(1) and failure to state a claim under Rule 12(b)(6). For example, Louisiana law for stipulations *pour autrui* (*i.e.*, third-party beneficiary contracts) suggests that failure to meet the promisee's conditions precedent renders third-

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[4] *See, e.g., Glock v. Howard & Wilson Colony Co.,* 123 Cal. 1, 16-17 (1898) (when a "contract is made to depend upon a condition precedent" and "[b]y its terms no right is to vest ... until certain acts ... have been done by [a party]," "a court of equity no more than a court at law will relieve [the party], under such circumstances ... in the absence of an equitable showing to excuse his default"); *Chen v. Chen,* 586 Pa. 297, 311-13, 893 A.2d 87, 96 (Pa. 2006) (third-party beneficiary lacked a "legally enforceable interest" and third-party standing based on terms of the agreement between the promisor and promisee); *Avatar Exploration, Inc. v. Chevron, U.S.A., Inc.,* 933 F.2d 314, 318 (5th Cir. 1991) (under Louisiana law, "[a]s third party beneficiaries, their rights under the contract could not exceed [the promisee's] rights").

party beneficiaries unable to state a claim. *Shaw Constructors v. ICF Kaiser Eng'rs, Inc.*, 395 F.3d 533, 540 & n.15 (5th Cir. 2004); *Kane Enter. v. MacGregor (USA) Inc.*, 322 F.3d 371, 375 (5th Cir. 2003). Even if unmet conditions precedent implicated only Rule 12(b)(6) *for promisees*,[5] they nonetheless would implicate jurisdiction for third-party beneficiaries, who lack standing to enforce non-vested rights. *Conoco, Inc. v. Republic Ins. Co.*, 819 F.2d 120, 123-24 (5th Cir. 1987); *Palma v. Verex Assur., Inc.*, 79 F.3d 1453, 1458 (5th Cir. 1996). Without the conditions precedent to PPA enforcement, Santa Clara has no legally protected interest in PPA reimbursement and thus lacks standing here.

Whether this Court adopts a federal rule of decision or relies on California law under *Miree*, third-party beneficiaries plainly lack standing to enforce contractual provisions that even the promisee could not enforce without having met the conditions precedent to contractual enforcement.

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[5] Numerous statutory regimes set conditions precedent to private enforcement to notify the putative defendant of alleged violations and to provide an opportunity to resolve them. *Zipes v. Trans World Airlines, Inc.*, 455 U.S. 385, 398 (1982); *Friends of the Earth, Inc. v. Laidlaw Envtl. Serv. (TOC), Inc.*, 528 U.S. 167, 174-75 (2000); *Hallstrom v. Tillamook County*, 493 U.S. 20, 32-33 (1989). Regardless of "whether the notice provision is jurisdictional or procedural," private enforcement is "barred" and "must be dismissed" if it commenced prior to the required notice. *Hallstrom*, 493 U.S. at 32-33. Even if that is not jurisdictional under constitutional standing, it is fatal under statutory standing, which this Court also can address at this stage. *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 830-31 (1999).

## II. SANTA CLARA HAS NO COMMON-LAW CAUSE OF ACTION TO ENFORCE THE PPA CONTRACTS

The Manufacturers convincingly demonstrate that HHS lacks authority to create a cause of action by contract that extends beyond the causes of action that Congress provided in the underlying statute. Manufacturers' Br. at 18-42. If it finds that Santa Clara has standing, *but see* Section I, *supra,* this Court should adopt a bright-line rule that the federal common law does not enable a federal agency to expand statutory causes of action beyond the express or implied statutory terms by regulation, contract, or otherwise: "Agencies may play the sorcerer's apprentice but not the sorcerer himself." *Alexander v. Sandoval,* 532 U.S. 275, 291 (2001).[6] The general rule of *Sandoval* applies even more strongly to this contract, where HHS claims not to have intended to create the private right of action in the first place.

Even if the Court declines to adopt a bright-line rule against agencies' expanding private causes of action, the Court nonetheless should find that *this contract* does not expand the private causes of action available to Santa Clara. Paragraph VII(g) of the PPA expressly provides that the PPA "shall be interpreted in the manner [that] best effectuates the statutory scheme." PPA ¶VII(g), Pet. App. 180a. All

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[6] Agency regulations can be enforceable if they implement the statute, as distinct from expanding the statute to prohibit (or allow) conduct that the statute does not prohibit (or allow). *Global Crossing Telecomm., Inc. v. Metrophones Telecomm., Inc.,* 550 U.S. 45, 59 (2007). Here, it is undisputed that the statutes in question do not provide a private cause of action.

of the reasons that the Manufacturers make for private enforcement's being foreign to the underlying statutes apply with even greater force to ¶VII(g)'s less-stringent inquiry into the mere consistency of private enforcement with the statutory scheme. Further, Paragraph VI(c) expressly provides that litigation between the Manufacturers and covered entities such as Santa Clara should proceed under the contract between those parties. PPA ¶VI(c), Pet. App. 177a. Thus, even without a bright-line rule for third-party enforcement of contracts generally, this Court should hold that *this contract* precludes third-party enforcement by entities such as Santa Clara.

## CONCLUSION

For the foregoing reasons, this Court should hold that Santa Clara lacks standing to bring its third-party claim to enforce the United States' PPA contract. If this Court finds that Santa Clara would have standing to enforce the PPA as a third-party beneficiary assuming *arguendo* that the federal common law provides such a cause of action, this Court nonetheless should hold that the federal common law *does not* provide such a cause of action.

November 18, 2010 Respectfully submitted,

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# AMICUS CURIAE BRIEF

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# In the Supreme Court of the United States

ASTRA USA, INC., ET AL., PETITIONERS

*v.*

COUNTY OF SANTA CLARA

*ON WRIT OF CERTIORARI*
*TO THE UNITED STATES COURT OF APPEALS*
*FOR THE NINTH CIRCUIT*

## BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

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*Gonzaga University* v. *Doe*, 536 U.S. 273 (2002) ..... 5, 6, 7, 8

*Grochowski* v. *Phoenix Construction*, 318 F.3d 80 (2d Cir. 2003) ..... 16

*Hollerbach* v. *United States*, 233 U.S. 165 (1914) ..... 13

*Illinois* v. *City of Milwaukee*, 406 U.S. 91 (1972) ..... 4

*Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Curran*, 456 U.S. 353 (1982) ..... 6

*Northwest Airlines, Inc.* v. *Transport Workers Union*, 451 U.S. 77 (1981) ..... 6

*Pinter* v. *Dahl*, 486 U.S. 622 (1988) ..... 13

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Cases—continued:

*Sosa* v. *Alvarez-Machain*, 542 U.S. 692 (2004) ..... 4, 6, 8
*Stoneridge Investment Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148 (2008) ..... 5, 8, 12
*Texas Industries, Inc.* v. *Radcliff Materials, Inc.*, 451 U.S. 630 (1981) ..... 4
*Transamerica Mortgage Advisors, Inc.* v. *Lewis*, 444 U.S. 11 (1979) ..... 11
*United States* v. *Seckinger*, 397 U.S. 203 (1970) ..... 5
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Statutes, regulations, and rule:

29 U.S.C. 793 ..... 16
31 U.S.C. 1352 ..... 16
41 U.S.C. 701 ..... 16
42 U.S.C. 256b(a)(1) ..... 7
42 U.S.C. 1396r-8(a)(1) ..... 10
42 U.S.C. 1396r-8(a)(5) ..... 10
42 U.S.C. 1396r-8(b)(3)(A)-(B) ..... 10
42 U.S.C. 1396r-8(b)(3)(C) ..... 10
42 U.S.C. 1396r-8(b)(3)(D) ..... 14
42 U.S.C. 1396r-8(b)(4)(B)(i) ..... 10
42 U.S.C. 1983 ..... 7
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Davis-Bacon Act, 40 U.S.C. 3141 *et seq.*:
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False Claims Act, 31 U.S.C. 3729 ..... 11
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Exec. Order No. 11,246, § 202, 30 Fed. Reg. 12,320 (1965), *reprinted in* 42 U.S.C. 2000e note ..... 16
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61 Fed. Reg. 65,412-65,413 (1996) ..... 10
61 Fed. Reg. 65,413 (1996) ..... 11
S. Ct. R. 37.6 ..... 2

Page

Miscellaneous:

Federal Procurement Data System, *Federal Procurement Report, FY 2007* <tinyurl.com/2007fpdsreport> ..... 15

Kevin R. Kosar, *Privatization and the Federal Government: An Introduction*, Congressional Research Service Report for Congress 16 (Dec. 28, 2006) <tinyurl.com/crsreport> ..... 15, 17

Martha Minow, *Public and Private Partnerships: Accounting for the New Religion*, 116 Harv. L. Rev. 1229 (2003) ..... 17

News Release, Department of Justice, *Aventis Pharmaceutical to Pay U.S. $95.5 Million to Settle False Claims Act Allegations* (May 28, 2009) <tinyurl.com/2009fca> ..... 11

# In the Supreme Court of the United States

No. 09-1273

ASTRA USA, INC., ET AL., PETITIONERS

*v.*

COUNTY OF SANTA CLARA

*ON WRIT OF CERTIORARI*
*TO THE UNITED STATES COURT OF APPEALS*
*FOR THE NINTH CIRCUIT*

## BRIEF FOR THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE SUPPORTING PETITIONERS

### INTEREST OF AMICUS CURIAE

The Chamber of Commerce of the United States of America (Chamber) is the Nation's largest federation of business companies and associations. It directly represents 300,000 members and indirectly represents the interests of over 3 million business, trade, and professional organizations of every size, in every business sector, and from every region of the country. A central function of the Chamber is to represent the interests of its members in important matters before the courts, Congress, and the Executive Branch. To that end, it files briefs as ami-

cus curiae in cases that raise issues of vital concern to the Nation's business community.[1]

This case presents a simple question of exceptional importance to the Chamber's members: *viz.*, whether a private plaintiff may sue as a third-party beneficiary of a government contract that incorporates the requirements of a federal statute where the statute itself does not confer a private right of action. In the decision under review, the Ninth Circuit held that a private plaintiff was entitled to pursue such a suit. That decision directly implicates the interests of the Chamber and its members.

Millions of American businesses annually enter into contracts with the federal government in a wide range of industries including construction, manufacturing, transportation, and utilities. Those contracts routinely track statutory or regulatory requirements, or require contracting parties to comply with those requirements as a condition of doing business with the government. Until the decision below, no court of appeals had permitted a private plaintiff to bring suit to enforce those requirements as a third-party beneficiary of the contract where, as is frequently the case, the plaintiff had no statutory right of action.

If the Ninth Circuit's decision were allowed to stand, it would have dire and sweeping consequences. Compa-

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[1] Pursuant to Rule 37.6, the Chamber affirms that no counsel for a party authored this brief in whole or in part; no such counsel or a party made a monetary contribution to fund its preparation or submission; and no person other than the Chamber, its members, or its counsel made such a monetary contribution. The parties have entered blanket consents to the filing of amicus briefs, and copies of their letters of consent are on file with the Clerk's Office. Counsel for the Chamber represents some of the petitioners on unrelated matters.

nies that do business with the government would be exposed to burdensome and expensive litigation, with the possibility of significant liability and the unjustified disclosure of confidential information. If adopted by this Court, the Ninth Circuit's approach would disrupt the settled expectations not only of the private sector, but also of numerous government departments and agencies that depend on the private sector to provide goods and services in a cost-effective manner—including, as in this case, goods and services that are vital to promoting the public welfare. And it would create a disincentive for businesses to enter into government contracts in the future—an outcome that would disserve the interests of millions of Americans whose lives are improved through public-private partnerships embodied in government contracts such as the ones at issue here. For those reasons, the Chamber and its members have a significant interest in the disposition of this case.

## SUMMARY OF ARGUMENT

The Ninth Circuit's decision in this case is patently erroneous. By permitting a private plaintiff to bring suit under the guise of federal common law in order to enforce a federal statutory requirement, the Ninth Circuit flouted this Court's repeated admonitions concerning the limitations on the invocation of federal common law and on the recognition of implied rights of action. Under a proper reading of the Court's decisions, the absence of a private right of action to enforce the statutory requirements at issue here forecloses efforts to enforce those requirements through other means. The Court should reverse the judgment below in order to bring the Ninth Circuit's aberrant mode of analysis in line with the Court's decisions.

If the Ninth Circuit's decision is allowed to stand, it would be extraordinarily harmful to American businesses, both in the immediate context and in many others. By using federal common law to permit a private party to bring suit, the decision below threatens to expose businesses to liability that neither they nor the federal government envisioned when entering into contractual arrangements implementing statutory requirements. And it would wreak havoc on statutory schemes (like the one at issue here) that by their terms contemplate the possibility only of government, and not of private, enforcement. Those dramatic consequences confirm the folly of the Ninth Circuit's approach.

## ARGUMENT

### A. The Court Of Appeals' Decision Is Erroneous

1. In the decision under review, the Ninth Circuit held that a private plaintiff was entitled to bring suit to enforce statutory requirements as a third-party beneficiary of a contract where the plaintiff had no statutory right of action. See Pet. App. 29a. That holding cannot be reconciled with this Court's decisions.

As the Court has recognized, "[t]here is, of course, 'no federal general common law.'" *Texas Industries, Inc.* v. *Radcliff Materials, Inc.*, 451 U.S. 630, 640 (1981) (quoting *Erie R.R. Co.* v. *Tompkins*, 304 U.S. 64, 78 (1938)). To be sure, the Court has permitted the fashioning of federal common law in "few and restricted instances." *Atherton* v. *FDIC*, 519 U.S. 213, 225 (1997) (internal quotation marks and citation omitted). Those instances involve certain "havens of specialty," *Sosa* v. *Alvarez-Machain*, 542 U.S. 692, 726 (2004), such as international relations, see *Banco Nacional de Cuba* v. *Sabbatino*, 376 U.S. 398, 424-427 (1964), and disputes between the States, see *Illinois* v. *City of Milwaukee*, 406

U.S. 91, 103-105 (1972). And to that end, the Court has held that federal common law governs the interpretation of contracts to which the federal government is a party. See, *e.g.*, *United States* v. *Seckinger*, 397 U.S. 203, 209-210 (1970).

The Court, however, has never sanctioned the use of federal common law as a means to enforce requirements in federal statutes that lack a private right of action. That is for good reason, because a claim by a private plaintiff seeking to enforce a statutory requirement on a third-party beneficiary theory is simply an implied right of action by another name. Particularly in recent years, the Court has repeatedly cautioned against judicial recognition of implied rights of action. See, *e.g.*, *Gonzaga University* v. *Doe*, 536 U.S. 273, 286 (2002) (explaining that, "where the text and structure of a statute provide no indication that Congress intends to create new individual rights, there is no basis for a private suit"); *Correctional Services Corp.* v. *Malesko*, 534 U.S. 61, 67 n.3 (2001) (warning that "we have retreated from our previous willingness to imply a cause of action where Congress has not provided one"); *Alexander* v. *Sandoval*, 532 U.S. 275, 286-287 (2001) (noting that "private rights of action to enforce federal law must be created by Congress," even if a private right of action might be "desirable * * * as a policy matter" or "compatible with the statute"). The Court has explained that "the Judiciary's recognition of an implied private right of action necessarily extends its authority to embrace a dispute Congress has not assigned it to resolve." *Stoneridge Investment Partners, LLC* v. *Scientific-Atlanta, Inc.*, 552 U.S. 148, 164-165 (2008) (internal quotation marks and citation omitted).

The Court has suggested, moreover, that permitting private plaintiffs to bring suit in the absence of an ex-

press right of action would be particularly problematic where, as here, such an implied private right of action would coexist with an express *government* enforcement mechanism. In such circumstances, the implied private right of action would "permit enforcement without the check imposed by prosecutorial discretion." *Sosa*, 542 U.S. at 727. Accordingly, the Court has explained, "the express provision of one method of enforcing a substantive rule suggests that Congress intended to preclude others." *Sandoval*, 532 U.S. at 290; see *Gonzaga*, 536 U.S. at 289-290 (refusing to recognize "individually enforceable private rights" in light of other "mechanism[s] that Congress chose to provide for enforcing" the statutory obligations at issue).

Finally with regard to the Court's jurisprudence, there is all the more reason not to permit a right of action to enforce a statutory requirement to be created under the guise of federal common law. Because federal common law is "subject to the paramount authority of Congress," *Northwest Airlines, Inc.* v. *Transport Workers Union*, 451 U.S. 77, 95 (1981) (citation omitted), it is only "resorted to in absence of an applicable Act of Congress." *City of Milwaukee* v. *Illinois*, 451 U.S. 304, 314 (1981) (brackets, internal quotation marks, and citation omitted). As a result, any private right of action to enforce a statutory requirement must be derived by "interpret[ing] the statute Congress has passed." *Sandoval*, 532 U.S. at 286. The absence of a private right of action in the statute at issue thus ends the analysis, because federal common law cannot confer a right of action where the statute does not. Cf. *Merrill Lynch, Pierce, Fenner & Smith, Inc.* v. *Curran*, 456 U.S. 353, 401 (1982) (Powell, J., dissenting) (noting the "fundamental legal error" of "basing a finding of an implied cause of action under a federal statute on common-law principles").

2. The Ninth Circuit's decision founders in the face of those well-established principles. There can be no doubt that, in its underlying claim, respondent is seeking to enforce the requirements of Section 340B of the Public Health Service Act, 42 U.S.C. 256b—the statute establishing the discounted-drug program in question. As is relevant here, Section 340B requires the Secretary of Health and Human Services (HHS) to enter into agreements with manufacturers of covered outpatient drugs under which "the amount required to be paid * * * to the manufacturer for covered drugs * * * purchased by a covered entity * * * does not exceed an amount equal to the average manufacturer price * * * reduced by the rebate percentage." 42 U.S.C. 256b(a)(1). Mirroring that statutory obligation, the standard pharmaceutical pricing agreement provides that each manufacturer "agrees * * * to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the [average manufacturer price] * * * reduced by the rebate percentage." Pet. App. 170a. The Ninth Circuit itself conceded that Section 340B "specif[ies] the * * * terms" of the contracts at issue here; that the contracts "closely track[]" the statutory language; and that the contracts further provide that "ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." *Id.* at 15a.

In addition, respondent has acknowledged that Section 340B confers no private right of action. See Pet. App. 22a. Under this Court's jurisprudence, that is the beginning and the end of the inquiry: because Congress accordingly cannot have "intend[ed] to create new individual rights" when it enacted Section 340B, "there is no basis for a private suit." *Gonzaga*, 536 U.S. at 286. That is true, moreover, regardless of whether the private plaintiff's suit is brought under 42 U.S.C. 1983, an im-

plied right of action, or a third-party beneficiary theory of the type respondent is advancing. *Gonzaga*, 536 U.S. at 286. No matter the precise mechanism invoked by the plaintiff, such a suit would implicate precisely the same interests, disrupting carefully calibrated statutory schemes and, in so doing, raising serious separation-of-powers concerns. See, *e.g.*, *Stoneridge*, 552 U.S. at 165 (observing that "[t]he determination of who can seek a remedy has significant consequences for the reach of federal power"); *Sosa*, 542 U.S. at 727 (stating that "[t]he creation of a private right of action raises issues beyond the mere consideration whether underlying primary conduct should be allowed or not").

3. The Ninth Circuit's justifications for its novel and expansive approach are unavailing.

a. In defense of its approach, the Ninth Circuit contended that the recognition of a private right of action here would be "wholly compatible with the [statute's] objectives." Pet. App. 26a. Even assuming that is so, it is insufficient to justify the recognition of either an implied right of action or a right of action based on federal common law. This Court long ago "abandoned" the notion that courts should "provide such remedies as are necessary to make effective the congressional purpose expressed by a statute." *Sandoval*, 532 U.S. at 287 (internal quotation marks and citation omitted); see *Central Bank of Denver, N.A.* v. *First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 188 (1994) (observing that "[p]olicy considerations cannot override our interpretation of the text and structure of [a statute]").

In any event, it is far from clear that recognition of a private right of action would actually advance the statute's objectives. In contending that it would, the Ninth Circuit, relying solely on a House committee report, concluded that the statutory purpose was to "giv[e] covered

entities discounts so they [can] stretch scarce Federal resources as far as possible." Pet. App. 27a (internal quotation marks and citation omitted). As the government argued below, however, the purpose of the statutory scheme is far more nuanced than the Ninth Circuit suggests: for example, while covered entities have an interest in lower average manufacturer prices (because they lead to lower maximum prices that the entities can be charged), the States actually have an interest in *higher* average manufacturer prices (because they lead to larger Medicaid rebates for the States). See Gov't C.A. Br. 31.

b. The Ninth Circuit additionally contended that recognition of a private right of action would be "sensible" because it would avoid "plac[ing] the entire burden of enforcement on the government." Pet. App. 27a. That contention, however, is wholly at odds with the government's own assessment that recognition of a private right of action "would conflict with Congress's comprehensive administrative and enforcement scheme[] and accord [private parties] contract rights never intended by the [contract's] signatories." Gov't C.A. Br. 21.

In contending that recognition of a private right of action was necessary to supplement the government's own enforcement mechanisms, the Ninth Circuit greatly understated the scope of those mechanisms—and thus the extent to which recognition of a private right of action would disrupt them. The Ninth Circuit did acknowledge that both HHS's own regulations and the standard pharmaceutical pricing agreement provide for dispute resolution if a manufacturer is believed to have overcharged covered entities. See Pet. App. 16a-17a, 26a, 174a; 61 Fed. Reg. 65,412 (1996) (stating that among the "[d]isputes resolved by" HHS's dispute resolution process is one in which "[a] covered entity believes that a

manufacturer is charging a price * * * that exceeds the ceiling price as determined by section 340B"). Those mechanisms are not trivial: if, after dispute resolution, the Secretary finds that a manufacturer has not complied with its statutory and contractual obligations, the Secretary may require the manufacturer to reimburse overcharged entities and may even terminate the agreement altogether. See Pet. App. 174a; 61 Fed. Reg. 65,412-65,413. The latter remedy is an especially severe punishment, because, in the absence of a pharmaceutical pricing agreement with HHS, *all* of a manufacturer's medicines are ineligible for Medicaid coverage. See 42 U.S.C. 1396r-8(a)(1), (a)(5).

As the Ninth Circuit failed to recognize, moreover, HHS wields additional tools by which it can enforce manufacturers' reporting of price data. Those tools are significant because, at bottom, a claim that covered entities were overcharged by a manufacturer will (as here) ordinarily turn on the premise that the manufacturer incorrectly reported data concerning average manufacturer and best prices—data, in turn, that determine the maximum price the manufacturer can charge. Under federal law, HHS can audit a manufacturer's calculations of average manufacturer and best prices, and it can survey manufacturers and wholesalers in order to verify the underlying data that a manufacturer submits concerning those prices. 42 U.S.C. 1396r-8(b)(3)(A)-(B). HHS can impose substantial monetary penalties for the submission of false or untimely data: $100,000 for "each item" of false information, and $10,000 for "each day" that a submission is untimely. 42 U.S.C. 1396r-8(b)(3)(C). HHS can also terminate a manufacturer's participation in the Medicaid rebate program for violation of applicable requirements. See 42 U.S.C. 1396r-8(b)(4)(B)(i). And in conjunction with the Department of Justice, HHS

can even bring suit against a manufacturer under the False Claims Act, 31 U.S.C. 3729—as HHS regulations expressly contemplate, see 61 Fed. Reg. 65,413, and as the government has done in at least one recent instance to the benefit of covered entities such as respondent. See News Release, Department of Justice, *Aventis Pharmaceutical to Pay U.S. $95.5 Million to Settle False Claims Act Allegations* (May 28, 2009) <tinyurl.com/2009fca> (noting that, as part of the settlement of a suit under the False Claims Act, a manufacturer agreed to pay over $6 million to covered entities that "paid inflated prices for the drugs at issue").

Because the government has numerous enforcement mechanisms at its disposal (and is evidently willing to use them), this is not a situation in which an alleged statutory violation is "in search of a remedy." *Malesko*, 534 U.S. at 74. And the availability of government enforcement mechanisms underscores the difficulty with the Ninth Circuit's approach, because it is an "elemental canon of statutory construction" that, when a statutory scheme "provides a particular remedy or remedies," a court should be "chary of reading others into it." *Transamerica Mortgage Advisors, Inc.* v. *Lewis*, 444 U.S. 11, 19 (1979).

In sum, the Ninth Circuit's decision is flatly inconsistent with this Court's precedents concerning the limitations on the recognition of private rights of action to enforce statutory requirements. And the Ninth Circuit's justifications for its novel approach are invalid. This Court should reject that approach and reverse the judgment below.

### B. If Adopted By This Court, The Court Of Appeals' Approach Would Have Devastating Consequences For American Companies That Contract With The Federal Government

A rule that permits private plaintiffs to bring suit to enforce statutory requirements as third-party beneficiaries would have far-reaching and profound consequences for the millions of American companies that do business with the federal government. If adopted by this Court, the Ninth Circuit's approach threatens not only to impose substantial costs on those companies, but to disrupt the operations of government departments and agencies and to disserve the interests of millions of Americans who benefit from public-private partnerships of the type at issue here. For those reasons, too, the Ninth Circuit's approach should be rejected.

1. This Court has long warned of the baleful consequences of expanding private enforcement of a federal statute through judicial fiat. Where a statute does not expressly confer a right of action, the judicial recognition of such a right disrupts the expectations of would-be defendants, who are suddenly forced to grapple with "extensive discovery," "the potential for uncertainty and disruption," and other litigation-related burdens that substantially raise the "costs of doing business." *Stoneridge*, 552 U.S. at 163-164. In many cases, those burdens will be sufficiently onerous as to "allow plaintiffs with weak claims to extort settlements from innocent [defendants]." *Id.* at 163; see *Bell Atlantic Corp.* v. *Twombly*, 550 U.S. 544, 558 (2007) (referring to litigation tactics that "take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value") (citation omitted). Where the defendant is a business, moreover, the costs of defending against such litigation will be either absorbed (and thus

borne by investors and employees) or passed on to consumers. See *Central Bank*, 511 U.S. at 189.

The foregoing concerns apply with even greater force where, as here, the question is whether to recognize a right of action to enforce a statutory obligation by means of a third-party contract claim. Contract law demands "certainty and predictability." *Central Bank*, 511 U.S. at 188 (citation omitted). As with any other type of contract, parties to a government contract seek to establish the full scope of their obligations and potential liabilities *ex ante*, by memorializing them in a written document that reflects the parties' mutual understanding. Cf. *Hollerbach* v. *United States*, 233 U.S. 165, 171 (1914) (noting that "[a] [g]overnment contract should be interpreted as are contracts between individuals, with a view to ascertaining the intention of the parties and to giv[ing] it effect accordingly"). Businesses, in particular, need clear and understandable rules to follow. See, *e.g.*, *Pinter* v. *Dahl*, 486 U.S. 622, 654 n.29 (1988). The expectations of the parties to a contract would be wholly disrupted if a court were to permit an alleged third-party beneficiary to bring suit—and thereby potentially to impose massive costs on one of the parties to the contract—for the purpose of enforcing an obligation in a statute that, by its terms, does not allow for private enforcement.

2. This case amply demonstrates the dangers of permitting suit under federal common law in the absence of an express right of action. It is undisputed that, in entering into the contracts at issue, neither petitioners nor HHS contemplated that Section 340B entities such as respondent would be able to sue as third-party beneficiaries to enforce petitioners' statutory obligations. See Gov't C.A. Br. 21 (noting that "HHS never imagined that a [Section] 340B entity could bring a third-party beneficiary lawsuit like [respondent's]"). Nor did petitioners

or HHS have any reason to expect such litigation, in light of the absence of a private right of action in Section 340B and the extensive enforcement mechanisms already at HHS's disposal. See *id.* at 13 (concluding that permitting third-party claims would "undermine HHS's role" in enforcing Section 340B); see generally pp. 9-11, *supra* (discussing enforcement mechanisms).

The Ninth Circuit's novel approach thus upended the previously settled expectations of both petitioners and the federal government. If adopted by this Court, that approach would disrupt the complex and carefully calibrated framework that Congress established for the administration and enforcement of the Section 340B drug-pricing and Medicaid rebate programs. In this case, moreover, the consequences would be particularly acute. Petitioners face the prospect of costly and extensive discovery—all on the basis of a handful of reports (one later rescinded) by HHS's Office of the Inspector General that do not even identify any specific manufacturers. See Pet. App. 99a, 109a-110a. And this litigation threatens not only to impose considerable burdens on petitioners, but potentially to reveal information concerning petitioners' pricing policies that was previously understood to be confidential. See 42 U.S.C. 1396r-8(b)(3)(D). Permitting this litigation to go forward would thus be inconsistent both with congressional intent in enacting Section 340B and with the broader government policy favoring public-private partnerships.

3. The highly detrimental consequences of recognizing a cause of action in the circumstances presented here, however, reach far beyond the immediate context of this case. A rule that permits private plaintiffs to bring suit to enforce statutory requirements as third-party beneficiaries could apply whenever a government contract incorporates an underlying statutory or regula-

tory requirement. The vast implications of such a rule confirm the necessity of rejecting it.

To begin with, the scope of federal contracting is enormous. One recent estimate suggests that there are more than *seven million* federal contractors. See Kevin R. Kosar, *Privatization and the Federal Government: An Introduction*, Congressional Research Service Report for Congress 16 (Dec. 28, 2006) (CRS Report) <tinyurl.com/crsreport>. In 2007 alone, American companies conducted approximately $460 billion of business with the federal government—more than twice as much as a decade earlier. See Federal Procurement Data System, *Federal Procurement Report, FY 2007*, at 2 <tinyurl.com/2007fpdsreport>. Some $70 billion of those contracts involved small businesses. See *id.* at 6. Even before the most recent spasms of growth in the size of government, government contracts constituted a substantial portion of diverse sectors of the national economy, including manufacturing ($164 billion in 2007); professional, scientific, and technical services ($123 billion); construction ($31 billion); transportation ($8 billion); and utilities ($2 billion). See *id.* at 31-34. And numerous government departments and agencies enter into sizable contracts with the private sector, including the Departments of Energy ($23 billion); Health and Human Services ($14 billion); and Veterans Affairs ($12 billion). See *id.* at 10-11. Those numbers, moreover, do not include federal grants to state and local governments, which often in turn direct the grants to the private sector in order to "construct and repair roads, build waste treatment plants, fund community renewal efforts, and so forth." CRS Report 18 n.82.

Unsurprisingly, when companies and the government enter into contractual arrangements, companies are often required to comply with statutory or regulatory re-

quirements as a condition of doing business with the government. To take but a few examples, the Davis-Bacon Act requires companies undertaking construction projects for the government to pay their workers according to a wage schedule set by the Department of Labor. See 40 U.S.C. 3142. The Rehabilitation Act requires companies doing business with the government to take "affirmative action" to employ disabled individuals. See 29 U.S.C. 793. Executive Order 11,246 requires companies doing business with the government to agree not to discriminate on the basis of race, creed, color, or national origin. See Exec. Order No. 11,246, § 202, 30 Fed. Reg. 12,320 (1965), *reprinted in* 42 U.S.C. 2000e note. And other federal laws require companies doing business with the government to "provide a drug-free workplace," 41 U.S.C. 701, and prohibit them from using appropriated funds for certain lobbying activities, see 31 U.S.C. 1352.

None of the foregoing provisions confers an express right of action to enforce its requirements; the same is true for the vast majority of other statutes applicable to government contractors. See, *e.g.*, *Grochowski* v. *Phoenix Construction*, 318 F.3d 80, 86 (2d Cir. 2003) (holding that plaintiffs' third-party beneficiary claims were "indirect attempts at privately enforcing" the Davis-Bacon Act, and deeming the claims "clearly an impermissible 'end run' around [the Act]"). The approach adopted by the Ninth Circuit, however, would replace the traditional understanding that the absence of a private right of action forecloses suit with an open-ended, speculative, and unpredictable analysis. The practical effect of such an approach would be to expose any company that has entered into a government contract incorporating an underlying statutory requirement to the potential of costly and unanticipated litigation. It would create a serious

disincentive for companies to engage in business with the government going forward. And it would impose burdens on the government itself, insofar as the government would have to provide greater compensation to offset the potential costs of third-party litigation and thereby induce companies to enter into government contracts. Such an approach cannot readily be reconciled with the Court's reluctance to adopt legal rules that "compromis[e] the Government's practical capacity to make contracts" and thereby undermine "the myriad workaday transactions of its agencies." *United States* v. *Winstar Corp.*, 518 U.S. 839, 884 (1996) (plurality opinion); see *id.* at 913 (Breyer, J., concurring) (explaining that the government must be "able to obtain needed goods and services from parties who might otherwise * * * be unwilling to undertake" government contracts).

Perhaps the most serious of the consequences of the Ninth Circuit's approach is the chilling effect it promises to have on business activity between the private and public sectors. "Since the founding of the Republic, the federal government has hired or contracted with private firms to provide public goods and services." CRS Report 2; see, *e.g.*, Act of Aug. 7, 1789, § 3, 1 Stat. 54 (requiring the Secretary of the Treasury to "provide by contracts * * * for building a lighthouse near the entrance of Chesapeake Bay"). The federal government has frequently turned to the private sector to provide goods and services to the American people in a cost-effective, high-quality, and reliable manner. Private entities now manage public schools, run prisons, oversee welfare programs, provide drug-abuse counseling, and offer employment training. See Martha Minow, *Public and Private Partnerships: Accounting for the New Religion*, 116 Harv. L. Rev. 1229, 1231-1232, 1267 (2003). And they are often integrally involved in major government policy in-

itiatives, as illustrated by the health-care programs at issue here.

By destabilizing existing government contracts and creating disincentives for companies to enter into new ones, the Ninth Circuit's decision disrupts the public-private partnerships that have long contributed to the well-being of the country and its citizens. To be sure, it is well established that private entities that do business with the government may not act with impunity. The same statutory provisions that authorize particular government contracts, however, must also establish any available enforcement mechanisms. And it is ultimately up to the political branches to decide what enforcement mechanisms to provide and who may invoke them. It is not the role of the Judiciary to substitute its judgment for that of the political branches and to create a common-law right of action that does not exist as a matter of statute. The Ninth Circuit's decision to arrogate such law-making authority to itself is erroneous and has far-reaching implications. The Court should reverse that decision and restore the preexisting understanding of the appropriate scope of private rights of action.

## CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted.

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# AMICUS CURIAE BRIEF

Supreme Court, U.S.
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No. 09-1273

IN THE
# Supreme Court of the United States

ASTRA USA, INC., ET AL.,
*Petitioners*,

v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,
*Respondent*.

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## BRIEF OF A COALITION OF 340B ENTITY GROUPS AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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H.R. Rep. 102-384,102d Cong., pt. 2, at 12 (2d Sess. 1992) ..... 4

*Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency*, Hearing Before the Subcomm. on Oversight and Investigations of the H. Committee on Energy and Commerce, 109th Cong., H. Hrg. 109-108 (2006), http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf ..... 26, 27, 28

**Administrative Materials**

Advanced Notice of Proposed Rulemaking and Request for Comments, 340 Drug Pricing Program Administrative Dispute Resolution Process, 75 Fed. Reg. 57233 (Sept. 20, 2010) ..... 34, 35

July 23, 2004 Letter from Sen. Charles E. Grassley to Hon. Tommy Thompson, HHS Secretary and Dr. Elizabeth M. Duke, HRSA Administrator ..... 25, 26

Manufacturer Audit Guidelines and Dispute Resolution Process, Health Resources and Services Administration, 61 Fed. Reg. 65406 (Dec. 12, 1996) ..... 12, 13

Office of Inspector General, Dep't of Health and Human Services:

*Appropriateness of 340B Drug Prices*, OEI-05-02-00070 (June 2004)..... 24

*Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, at 15 (Oct. 2005), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf..... 16, 27

*Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, A-06-01-0060, at 4 (Mar. 2003) http://oig.hhs.gov/oas/reports/region6/60100060.pdf..... 16, 24, 25

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**Other Authorities**

HRSA, *About the Ryan White HIV/AIDS Program* (2010), http://hab.hrsa.gov/aboutus.htm ..... 7

HRSA, *Enrollment in 340B Program to Provide Affordable Medications Begins for Newly Eligible Safety-Net Health Care Providers* (Aug. 2, 2010)... 5

HRSA, *Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program*

*Established by Section 340B of the Public Health Service Act*, (July 2005), http://www.hrsa.gov/ hemophiliatreatment/340Bmanual.htm ..... 4, 5
*HRSA Requests Refunds from Rx Manufacturers*, Federal Drug Discount and Compliance Monitor, Vol. 1, No. 5 (November 2004), p. 1. ..... 26
Larry S. Gage & William von Oehsen, *Managed Care Manual: Medicaid and State Health Reform* (1995). ..... 10
National Association of Community Health Centers (2010), http://www.nachc.org/ ..... 6, 7
National Association of Public Hospitals and Health Systems, *America's Public Hospitals and Health Systems, 2008* (Feb. 2010), http://www.naph.org/ Main-Menu-Category/Publications/Safety-Net-Financing/Characteristics-2008.aspx ..... 6
Planned Parenthood Action Center, *340B Programs Help Low-Income Individuals and Their Health Care Providers*, (2010), http://www.plannedparenthoodaction.org/positions/ 340b-program-helps-low-income-individuals-their-health-care-providers-628.htm ..... 9
Public Hospital Pharmacy Coalition, *Access to IVIG By Safety Net Hospitals Participating in the 340B Drug Discount Program*, at 7 (Sept. 2006), http://www.ashp.org/ s_ashp/docs/files/ DShort_IVIGAccesssafetynethospSept06.pdf ..... 19
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## INTEREST OF *AMICUS CURIAE*[1]

Amicus curiae is a coalition ("Coalition") of eight organizations that collectively represent thousands of "safety net" providers and programs throughout the United States that participate in the 340B drug discount program. These safety net providers – otherwise known as "covered entities" – furnish or arrange for health care services to disproportionately high numbers of patients who are indigent, uninsured, underinsured, chronically ill, and/or otherwise vulnerable. As such, they qualify to participate in the Public Health Service 340B Drug Pricing Program ("340B program"), which entitles them, if they enroll, to receive deep discounts on covered outpatient drugs. 340B providers are highly dependent on public funding – including federal grants, Medicaid, Medicare and state and local subsidies – so the discounts they receive under the program allow them to stretch their tax-supported dollars further in caring for our nation's poorest and most vulnerable populations. The eight Coalition members are:

- Hemophilia Alliance
- National Alliance of State and Territorial AIDS Directors
- National Association of Counties
- National Association of Public Hospitals and Health Systems

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amicus curiae* represents that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel, nor any other person or entity other than *amicus*, its members, or their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amicus* also represents that all parties have consented to the filing of this brief, and letters reflecting their blanket consents to the filing of *amicus* briefs have been filed with the Clerk.

- National Family Planning and Reproductive Health Association
- National Health Care for the Homeless Council
- Planned Parenthood Federation of America
- Safety Net Hospitals for Pharmaceutical Access

The Coalition files this brief to apprise the Court of the insufficiency of the 340B administrative enforcement program for the periods at issue here. The Coalition has worked for years to solicit government support in investigating and remedying overcharge problems and to gain enhanced federal enforcement in assuring that its members are charged no more than the correct 340B ceiling prices. Congress was well aware of the agency's inability to engage in stringent enforcement measures, and it sought to resolve these problems when it enacted the Patient Protection and Affordable Care Act ("PPACA"), Pub. L. No. 111-148 (Mar. 23, 2010), 124 Stat. 119 (2010). By its terms, however, PPACA applies only to drugs purchased on and after January 1, 2010. PPACA, §7101(e)(1). As such, its remedial protections are not available as to the claims raised in this case.

## SUMMARY OF ARGUMENT

For the periods at stake here, the court of appeals correctly recognized that the administrative enforcement framework for the 340B program was fatally flawed both in theory and practice. On paper, the operative statutory and pharmaceutical pricing agreement ("PPA") provisions lacked meaningful procedures or mechanisms to enable covered entities to pursue administrative grievances as to drug pricing or to allow the relevant federal oversight agency, the Health Resources and Services Administration

("HRSA"), to redress those complaints. The sole means for covered entities to do so involved an informal dispute resolution process that was entirely voluntary in nature. In practice, HRSA's informal dispute resolution process has been invoked infrequently not only because of its voluntary nature but also because HRSA has been ill-equipped to pursue or investigate complaints or to issue meaningful determinations on claims that were filed. The evidence as to the inefficacy of the 340B administrative enforcement process is overwhelming and irrefutable.

Indeed, when it established the 340B program, Congress deliberately directed that the Secretary of the Department of Health and Human Services ("Secretary" and "HHS") enter into contractual PPAs with drug manufacturers – contracts that would invariably result in legal rights accruing to affected third-party beneficiaries, including covered entities. There is no evidence – and petitioners have cited none – that Congress was unaware of or oblivious to the implications of that mandate for covered entities seeking to exercise their new rights. Certainly, Congress was entitled to make the judgment that the ability of third-party beneficiaries to vindicate their contractual rights in court would protect them from any deficiencies or lapses in administrative enforcement.

Later, Congress became starkly aware of these significant administrative enforcement failings, and with the enactment of PPACA erected a much more rigorous administrative enforcement process to cover claims on and after January 1, 2010. Congressional recognition of the necessity for such reforms should not be construed, however, as evidence that Congress has always relied upon and preferred administrative

enforcement. Rather, it should be interpreted as a recognition by Congress that the existing administrative enforcement process was wholly inadequate. These factors – Congress's earlier mandate that contracts be utilized and its later determination that administrative enforcement was insufficient – should weigh heavily in allowing contractual actions by covered entities to bolster enforcement on pre-PPACA claims.

## ARGUMENT

### I. COVERED ENTITIES ARE THE INTENDED BENEFICIARIES OF THE PROGRAM AND ARE HEAVILY DEPENDENT ON 340B SAVINGS TO SUPPORT THEIR SAFETY NET MISSION

According to the 340B program's legislative history, Congress enacted the 340B law to enable covered entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." H.R. Rep. 102-384,102d Cong., pt. 2, at 12 (2d Sess. 1992). HRSA's elaboration of this congressional intent is instructive.

> The purpose of the 340B program is to lower the cost of acquiring covered outpatient drugs for selected health care providers so that they can stretch their resources in order to serve more patients or improve services. Additional program resources are generated if drug acquisition costs are lowered but revenue from grants or health insurance reimbursements are maintained or not reduced as much as the 340B discounts. [2]

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[2] HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section (cont'd)

It is therefore evident that, by establishing the 340B program, Congress intended to benefit not only safety net providers but also the taxpayers on whom these providers are so dependent for funding. Because lower cost drugs create "additional program resources" for 340B providers, taxpayers do not have to shoulder as much of the cost of indigent care.

Covered entities eligible for participation in the 340B program include certain high-Medicaid disproportionate share hospitals ("DSH"), as well as specified federal grantees, including federally qualified health centers ("FQHCs"), FQHC "look-alikes," state-operated AIDS drug assistance programs ("ADAPs"), Ryan White CARE Act Part A, Part B, and Part C Programs, tuberculosis, black lung, family planning and sexually transmitted disease clinics, hemophilia treatment centers, public housing primary care clinics, homeless clinics, Urban Indian clinics, and Native Hawaiian health centers. Most recently, under PPACA, several new covered entities have been deemed eligible for 340B program participation, including critical access hospitals and certain freestanding cancer hospitals, freestanding children's hospitals, rural referral centers, and sole community hospitals. According to the government, over 14,000 covered entity sites participate in the 340B program.[3]

Covered entities serve high volumes of the nation's most vulnerable, and often most impoverished, patient populations. The 340B law lists 17 categories of covered entities. Among them are the following:

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340B of the Public Health Service Act (July 2005), http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm.

[3] HRSA, *Enrollment in 340B Program to Provide Affordable Medications Begins for Newly Eligible Safety-Net Health Care Providers* (Aug. 2, 2010).

***Public hospitals*** – Providing more than 43 million ambulatory care visits annually,[4] public hospitals offer the full spectrum of high quality, coordinated health care to their communities, regardless of an individual patient's ability to pay. They provide 19 percent of uncompensated hospital care nationwide, even though they represent just two percent of the nation's hospitals. As a result of the patient populations they serve, safety net hospitals operate with exceptionally thin margins and rely on public programs like Medicaid and the 340B program to continue to provide appropriate health care services to vulnerable, low-income patients. In 2008, Medicaid and other government programs accounted for nearly two-thirds of these hospitals' net revenues. More than 80 percent of the increase in overall patient care volumes during the second quarter of 2010 (compared to the beginning of the recession) is due to serving additional uninsured or Medicaid patients.[5]

***Community health centers*** – Health centers serve 1 in 7 uninsured individuals nationally, including 1 in 5 of the low income, uninsured. Their patient populations include the homeless, residents of public housing, migrant farm workers, and others with emergent and chronic care needs. Approximately 70 percent of health center patients live in poverty.[6] Community health centers save the national

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[4] National Association of Public Hospitals and Health Systems, *America's Public Hospitals and Health Systems, 2008* (Feb. 2010), http://www.naph.org/Main-Menu-Category/Publications/Safety-Net-Financing/Characteristics-2008.aspx.

[5] The 340B Coalition, *340B Program Expands Access to Pharmaceutical Care and Reduces Cost to Taxpayers* ("Expands Access").

[6] National Association of Community Health Centers ("NACHC") (2010), http://www.nachc.org/. Because (cont'd)

health care system between $9.9 billion and $17.6 billion annually by helping patients to avoid emergency rooms and make better use of preventive services.[7]

***Ryan White clinics and programs*** – The Ryan White Program provides primary health care, pharmaceutical treatments, and support services for low-income people with HIV/AIDS and treats over 500,000 HIV-positive individuals in all 50 states, the District of Columbia, Puerto Rico and the Pacific Island jurisdictions. According to the Centers for Disease Control and Prevention, approximately 1,039,000 to 1,185,000 people in the country are living with HIV; of those individuals, approximately 421,873 are living with AIDS. Through public health systems, nonprofit clinics, community health centers and other providers, the Ryan White Program is designed to be the payer of last resort for individuals with HIV and AIDS.[8]

***Hemophilia treatment centers*** – Hemophilia treatment centers provide comprehensive care to individuals with bleeding and clotting disorders. Mor-

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FQHCs operate under a comprehensive regulatory scheme under 42 U.S.C. §254b and 42 U.S.C. §1396d, which afford them unique status under federal law, NACHC is not taking a position in this case. However, accounting for the circumstances of the parties to the brief who have attempted to have overcharges and other issues resolved through the processes described, NACHC concludes that the process had no teeth and in no instance was effective in correcting an alleged violation or other violation. According to NACHC, it is unimaginable that Congress would have impaired or intended to impair rights of actual enforcement that would inhere to the individual entities covered by the law.

[7] Id.

[8] HRSA, *About the Ryan White HIV/AIDS Program* (2010), http://hab.hrsa.gov/aboutus.htm.

tality rates and hospitalization rates for bleeding complications from hemophilia are 40 percent lower among people who receive care in hemophilia treatment centers than among those who do not receive this care. Significant medical cost savings are realized over the life of the patient through these centers.[9]

***Family planning clinics*** – Federally-funded family planning clinics are focused on providing preventive care to keep women, men and teens healthy, and to help women and couples plan their families. Each year, these grantees and sub-grantees provide essential health care, including routine gynecological exams, breast and cervical cancer screenings, contraceptive services, sexually transmitted infection testing and treatment, and HIV testing and education to more than three million patients, the vast majority of whom have incomes at or below 150 percent of the federal poverty level. More than six in 10 patients who receive care at women's health centers consider it their primary source of health care, which makes these centers a critical entry point into the health care system for millions of low-income, uninsured and underinsured individuals.

Covered entities often act as the "medical home" for their patients, offering primary care, family planning, mental health services, maternal and child health care, and health education and social service support such as teenage pregnancy programs, substance abuse education, and child abuse prevention. Because their patient populations are disproportionately represented by African Americans, Native

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[9] The Hemophilia Alliance, *The 340B Program & Hemophilia* (2010), http://hemoalliance.org/documents/AllianceBro_final2_D0034182.pdf.

Americans, Asians, Latinos and other ethnic or racial groups, they are dedicated to providing services in the language of their constituency and in a culturally sensitive manner.

Covered entities also serve a disproportionate share of patients with special health care needs, including the elderly, low-income children and families, trauma patients, victims of violent crime, and persons with chronic conditions such as HIV/AIDS, hemophilia, tuberculosis, mental illness, and diabetes. Many of these patients are from homeless shelters, school-based clinics, juvenile centers, and other governmental facilities. [10]

Covered entities play a vital role in the lives of their patients. In 1992, the year that the 340B law was enacted, Congress heard testimony about the critical role of safety net providers in serving the Medicaid population. Testimony by the executive director of a Los Angeles clinic – which subsequently enrolled in the 340B program as a Ryan White grantee, family planning clinic, and community health center – was particularly compelling. In the testimony, the executive director recounted a series of circumstances in which the clinic had made a profound difference in its patients' lives and health. In one example cited by the executive director, a woman came to regard the clinic as a lifeline and the center of her family and universe after testing positive for HIV. In another example, when a prenatal patient developed severe anemia, health educators from the clinic discovered that her Special Supplemental Food

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[10] Planned Parenthood Action Center, *340B Programs Help Low-Income Individuals and Their Health Care Providers* (2010), http://www.plannedparenthoodaction.org/positions/340b-program-helps-low-income-individuals-their-health-care-providers-628.htm.

Program for Women, Infants and Children Program allotment was being consumed by the nine other members of her household. The support staff met with the woman's housemates and explained the importance of reserving enough food for the woman and her unborn child. On another occasion, a prenatal patient confided to clinic staff that she wanted labor induced early, so that her boyfriend would stop beating her. After receiving counseling and a referral to a shelter, the woman gave birth and named the child after the clinic counselor. Finally, the executive director recounted a circumstance in which the cultural sensitivity and shared cultural experience of clinic staff played a vital role in dissuading a young man from committing suicide rather than disclose to his family that he was HIV positive.[11]

Overall, 340B covered entities collectively serve as the nation's healthcare "safety net," providing care and treatment to the neediest among us, regardless of ability to pay. For these entities, the 340B program is a vital and indispensable tool to help offset the costs of uncompensated or under-compensated care. The program enables covered entities to maximize their resources to meet the health care and pharmaceutical needs of the fragile communities they serve. Without the 340B program, many pharmacies would be forced to restrict access greatly or, in some cases, shutter their doors. For these reasons, ensuring the accuracy of 340B discounts and protecting against manufacturer overcharges that deplete covered entities' limited resources are of critical importance to covered entities and the individuals they serve.

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[11] Larry S. Gage & William H. von Oehsen, *Managed Care Manual: Medicaid and State Health Reform* 7-4 (1995).

## II. THE 340B PROGRAM WAS DEVOID OF AN EFFECTIVE ADMINISTRATIVE ENFORCEMENT MECHANISM FOR ADDRESSING MANUFACTURER OVERCHARGES

The petitioners assert that, in this case, "Congress has 'occupied the field through the establishment of a comprehensive regulatory program supervised by an expert administrative agency.'" Petitioners' Brief at 44, *quoting City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981). From this, they reason that any private remedies for 340B entities must be limited to those established by Congress and that, since Congress did not expressly provide such a remedy, there is none. *Id. See also Middlesex Cnty Sewage Auth. v. Nat'l Sea Clammers Assoc.*, 456 U.S. 1, 21-22 (1981); *Northwest Airlines, Inc. v. Transp. Workers Union of Am.*, 451 U.S. 77, 93-94 (1981).

A careful examination of the administrative enforcement framework prior to the recent enactment of PPACA reveals, however, that it was neither elaborate nor extensive. Indeed, it was skeletal in nature and has therefore prevented the agency from providing meaningful program oversight and enforcing program requirements. This fact prompted Congress to alter the enforcement framework radically in PPACA.

### A. There Were No Viable Or Effective Administrative Remedies To Protect Against Manufacturer Non-Compliance

The pre-PPACA 340B statute itself contained no administrative enforcement mechanisms. *See* 42 U.S.C. §256b (2009). The Medicaid drug rebate statute did specify that, if the Secretary terminated a Medicaid drug rebate agreement, the termination also extended to the manufacturer's 340B PPA. 42

U.S.C. §1396r-8(b)(4)(B)(iv). As described later, both Congress and the HHS Office of Inspector General ("OIG") were concerned about the lack of meaningful administrative enforcement tools under 340B, and the agency itself conceded that the termination sanction was so draconian and potentially counterproductive that it was not utilized.

Likewise, there are no 340B administrative enforcement regulations issued by the agency, a reflection undoubtedly of the paucity of statutorily based enforcement tools accorded it.

The statutorily required PPA for the 340B program does include an enforcement mechanism not directly referenced in the statute.[12] Under that agreement, the Secretary may initiate an informal dispute resolution process with drug manufacturers based on alleged non-compliance, failure to submit required reports, or submission of false information. By its own terms, however, the process does not preclude manufacturers or the Secretary from exercising such other remedies as may be available by law. PPA at ¶ IV(c).

More importantly, when HRSA developed published standards pertaining to the informal dispute resolution process, it imposed major restrictions that have hamstrung any effective administrative enforcement. 61 Fed. Reg. 65406 (Dec. 12, 1996). Although the standards were avowedly designed to cover all types of 340B claims that drug manufacturers might have against 340B covered entities and that 340B covered entities might have against drug manufacturers (*id.* at 65412), they also contained

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[12] The version of the PPA relied upon by the parties is reprinted at Pet. App. 165a-181a.

significant limitations that the agency itself took repeated pains to emphasize:

> The Department is overseeing the implementation of section 340B of the PHS Act and as such, is offering a ***voluntary*** dispute resolution mechanism to expedite this process. ***No manufacturer or covered entity is required to avail itself of this process before resorting to other available measures.*** *** The dispute resolution process is a ***voluntary*** process. Manufacturers or entities are only encouraged to participate in the process before seeking other remedies.

*Id.* at 65411 (emphasis added).[13]

The voluntary nature of this informal dispute resolution process eviscerated any effectiveness it might have otherwise had. No manufacturer or entity, alleged to have violated 340B requirements, was likely to submit itself to the process. Indeed, as reflected in the sections below, despite significant and repeated efforts by 340B entities to draw the agency's attention to issues and problems, such complaints were subsumed by an administrative black hole from which they never emerged.

In light of this, it is odd that the United States admits that States may file suits against drug manufacturers to enforce Medicaid drug rebate obligations but claims that 340B entities could not do so to redress 340B claims. Brief for the United States at 34 n.14. As such, the United States reaches the paradoxical conclusion that non-federal entities involved

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[13] The agency never explained what these other available measures or remedies were, although it appeared to concede that they existed.

in the Medicaid drug rebate program may sue to enforce the requirements of that program but that the intended beneficiaries of the 340B program were powerless to do so despite the absence of a meaningful and rigorous administrative enforcement process. The Coalition has no doubt that the ability of States to bring such actions is essential to the Medicaid drug rebate program's enforcement structure. At the same time, however, there is absolutely no reason to think that legal actions by 340B entities will somehow upset or erode the federal government's administrative enforcement of the 340B program, especially given the tenuous nature of that enforcement as the Coalition now explains.

### B. In Actual Practice, Manufacturers Can Overcharge Covered Entities With Impunity

In the sections that follow, the Coalition presents examples of the inefficacy of HRSA's dispute resolution process as well as the agency's limited ability to respond to appeals for oversight by covered entities and Coalition members. These examples make clear that the pre-PPACA dispute mechanism, as referenced in the PPA and HRSA guidelines, was a vacant promise that did not, to the best of the Coalition's collective knowledge, function to resolve a single dispute involving alleged 340B overcharges against a manufacturer. [14] This failure may be traced to the lack of adequate funding and resources for HRSA as well as the lack of an effective oversight

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[14] In preparation for the drafting of this brief, SNHPA submitted an expedited Freedom of Information Act request to HRSA on Nov. 8, 2010, seeking a list of all dispute resolution claims filed with the agency since the 340B program's inception as well as the status of each claim. No response has yet been received.

and enforcement mechanism that could be utilized by the agency.

The Court may note that most of the examples involve Safety Net Hospitals for Pharmaceutical Access ("SNHPA"), which represents over 600 of the hospitals participating in the 340B program, including DSH, children's, and rural hospitals. SNHPA is the only Coalition member that advocates exclusively on drug pricing matters, especially issues relating to the 340B program. As such, SNHPA often undertakes initiatives that benefit not only its member hospitals, but also the broader 340B provider community. The examples described below are among those initiatives.

In reciting these examples, the Coalition does not want to imply that manufacturers never took corrective action to address past overcharges nor that HRSA was completely unhelpful in facilitating such actions. To the contrary, there are several instances in which manufacturers and HRSA worked together to make sure that covered entities were made whole after an overcharge was discovered. In each of these instances, however, the remedial actions were initiated by the manufacturer or were otherwise possible based on the manufacturer's willingness to cooperate. The concerns raised here relate to situations in which manufacturers have been uncooperative in addressing pricing disputes. The Coalition's point is that, in instances where manufacturers may be uncooperative, there is no effective administrative measure to remedy the disputes. The Coalition also recognizes that HRSA has had to cope with the lack of an adequate enforcement framework with which to ensure program compliance. The examples set forth in this portion of the Coalition's brief should thus not

be construed as being critical of the agency itself but of the limitations of the enforcement and oversight framework within which the agency has had to operate.

Accordingly, in light of the facts set forth below, and given that the OIG has repeatedly noted that HRSA lacked the authority and resources to monitor the 340B program adequately,[15] petitioners' assertion that covered entities had an adequate remedy in the existing dispute resolution mechanism is a hollow one. Moreover, limiting covered entities to a remedy that has repeatedly been shown to be ineffectual serves to foreclose them from any remedy at all. This is an unfathomable result which, although indisputably in the best interests of the petitioners, would leave 340B providers, and the taxpayers who support them, utterly unprotected from drug overcharges that threaten to deplete the "scarce resources" that the 340B program was specifically intended to protect.

*1. Use Of The Dispute Resolution Process Failed*

Over the past decade, the Coalition and its members have made repeated attempts to bring manufacturer overcharge problems to the attention of the agency, and to seek agency intervention to address these problems. In many instances, covered entities made specific requests for dispute resolution which were left unaddressed by HRSA, whether due to lack

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[15] OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, at 15 (Oct. 2005), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf; OIG, *Pharmaceutical Manufacturers Overcharged 340B-Covered Entities*, A-06-01-0060, at 4 (Mar. 2003), http://oig.hhs.gov/oas/reports/region6/60100060.pdf. ("2003 Report").

of resources, staff, or authority. In this section, the Coalition presents a few examples of the overall failings of the voluntary dispute resolution mechanism, as to alleged manufacturer overcharges.

On May 26, 2009, SNHPA, on behalf of eight member hospitals, filed a request for dispute resolution with HRSA regarding drug manufacturer Nycomed's refusal to provide 340B discounts for the drugs Digifab and Crofab.[16] These drugs are often used in hospital emergency departments to counteract an overdose of digoxin (used for treatment of various heart conditions) and as an antivenin to treat snake bites. Despite the fact that these drugs were properly considered "covered outpatient drugs" for which 340B discounts should have been available, Nycomed refused to provide 340B discounts to covered entities or, in the alternative, imposed overly-burdensome reporting requirements for emergency room use.[17]

In its request for dispute resolution, SNHPA noted that, prior to exercising its option to invoke HRSA's voluntary dispute resolution process, it had made good faith efforts to resolve the dispute directly with Nycomed. Given the lack of success of these efforts, SNHPA requested that HRSA intervene:

> [w]e ask your assistance in requiring Nycomed to provide a 340B price for Crofab and Digifab

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[16] Letter from Stuart Gordon, Director, Legal and Regulatory Affairs, SNHPA, to Jimmy Mitchell, HRSA Office of Pharmacy Affairs ("OPA") Director (May 26, 2009).

[17] This reporting requirement violated longstanding HRSA guidelines that prohibit manufacturers from requiring covered entities to fill out forms or perform other tasks as a condition of receiving 340B discounts. Requiring additional documentation from covered entities also violated HRSA's audit guidelines, which provide that audits may not be performed absent the submission of an audit workplan to HRSA. Id.

> and credit the purchases of covered outpatient drugs made by the [petitioning] hospitals with the applicable discount amount for the period of time that a 340B price has not been provided.[18]

SNHPA followed up repeatedly with HRSA regarding the status of the dispute resolution request between the months of June 2009 and May 2010. During that time, HRSA failed to process or adjudicate the complaint or to take any steps toward achieving a resolution. Crofab and Digifab did finally appear on wholesaler lists at 340B prices for the second quarter of 2010, although this development was voluntary on the manufacturer's part and not the result of HRSA intervention. Still, the matter is not fully resolved: the recent availability of these drugs at 340B prices does not relieve Nycomed of the obligation to provide retroactive refunds to 340B providers, back to 2001. These discounts, to which covered entities were lawfully entitled and which now span a nine-year period, represent a substantial debt that remains unaddressed as a result of HRSA's inability to follow through on SNHPA's dispute resolution request, which specifically requested intervention "for the period of time that a 340B price has not been provided."[19]

HRSA also did not respond to a dispute resolution request pertaining to manufacturers' refusals to provide 340B pricing on an expensive specialty drug, by incorrectly claiming that the drug was unavailable. This was the case with respect to intravenous immune-globulin ("IVIG"), a sterile preparation of concentrated antibodies recovered from the pooled plas-

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[18] Id.

[19] Id.

ma of healthy donors. IVIG plasma products are used to manage serious conditions, including immune system disorders and related illnesses.[20]

In the late 1990's, SNHPA learned that its member hospitals were having difficulty procuring sufficient amounts of IVIG to meet the needs of their patients. SNHPA members also complained that, even when they were able to obtain an adequate amount of IVIG, it was only available at prices that were higher than the statutory ceiling price to which they were entitled.[21] The limited availability of IVIG at 340B prices was a serious concern for covered entities, especially because expensive specialty drugs like IVIG products comprise a large portion of many hospitals' outpatient pharmacy expenses.[22]

In an effort to gain a more comprehensive understanding of these problems, SNHPA conducted a survey of its members regarding the accessibility of IVIG. The survey results revealed that, although only about 20 percent of its member hospitals were able to procure IVIG at 340B prices, a much higher percentage – approximately 70 percent – were able to obtain at least some amount of IVIG at higher prices from a wholesaler or other drug distributor.[23] Thus, according to the SNHPA study, IVIG was frequently available for purchase, but not at the discounted 340B prices to which covered entities were legally entitled. In sum, manufacturers appeared to be impro-

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[20] Public Hospital Pharmacy Coalition, *Access to IVIG By Safety Net Hospitals Participating in the 340B Drug Discount Program*, at 7 (Sept. 2006), http://www.ashp.org/s_ashp/docs/files/DShort_IVIGAccesssafetynethospSept06.pdf.

[21] Id. at 6.

[22] Id.

[23] Id. at 5.

perly withholding 340B sales to covered entities in lieu of higher prices charged under more lucrative, commercial contracts.

In July 2006, frustrated by manufacturers' intransigence, a SNHPA member hospital notified HRSA via e-mail of its problems in purchasing IVIG at 340B prices. Specifically, the hospital representative noted that, while it had been unable to purchase IVIG at 340B prices, it had been able to obtain the product at non-340B prices. In response to this correspondence, HRSA asked whether, through its e-mail, the hospital was requesting that the agency initiate the dispute resolution process. The hospital representative assented, stating that "[i]t seems that the informal dispute resolution process...would be the appropriate way to address the unavailability of IVIG at 340B prices...please proceed as appropriate and help me know what other information might be needed as you move forward." HRSA did not act upon this dispute resolution request and never followed up with the hospital regarding the request or to ask for additional information.[24]

*2. Requests For HRSA To Intervene Or Take Action Failed*

While HRSA has had some success in informally facilitating refunds to covered entities for manufacturer overcharges outside of the dispute resolution process, the agency's successes are necessarily limited to circumstances in which manufacturers have been willing to provide such refunds. Moreover, until the last few years, HRSA has not received direct funding from Congress to administer the 340B pro-

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[24] Email from Burnis Breland, Columbia Regional Healthcare System Director of Pharmacy and Clinical Research to Jimmy Mitchell, HRSA OPA Director (July 31, 2006).

gram and, therefore, OPA has had to rely upon fewer than ten dedicated employees. Perhaps for these reasons, even where covered entities or Coalition members have made general appeals for information or intervention in light of suspected or proven overcharges, HRSA has often remained unresponsive. For example, between June 2004 and October 2005, SNHPA and its members sent at least six e-mails to HRSA regarding potential 340B overcharges, but received no meaningful response from HRSA.

First, on June 11, 2004, SNHPA sent an e-mail to HRSA on a member's behalf inquiring why a manufacturer's 340B price for propofol was higher than the group purchasing organization ("GPO") price.[25] The inquiry did not receive a response. In July 2005, SNHPA contacted HRSA twice on behalf of another member to inquire why a manufacturer had not provided the member with information on 340B pricing.[26] HRSA responded that it was "trying to get in touch with the manufacturer," but provided no further response on the issue.[27] Again, on October 15, 2005, SNHPA sent an e-mail to HRSA on behalf of a member to inquire why the Hospira GPO price was lower than the 340B price.[28] On October 25, 2005, SNHPA sent another e-mail to HRSA asking for clarification as to why the Hospira GPO price was lower

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[25] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (June 11, 2004).

[26] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (July 5, 2005); email from Ted Slafsky, SNHPA Executive Director, to HRSA (July 18, 2005).

[27] Email from HRSA to Ted Slafsky, SNHPA Executive Director (July 22, 2005).

[28] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (Oct. 15, 2005).

than the 340B price.[29] SNHPA did not receive a response to either inquiry.

Similarly, on October 10, 2005, a SNHPA member alerted SNHPA that the 340B pricing for Lilly insulins ($20 per vial) was almost 50 percent higher than the GPO price ($11 per vial).[30] SNHPA asked HRSA to look into the matter, [31] and HRSA responded with general information about Lilly inpatient pricing and encouraged the member to convert the prime vendor pricing to obtain lower a price.[32] On October 11, 2005, the SNHPA member replied to this ambiguous response, and asserted that HRSA's prime vendor program suggestion "still doesn't explain why PHS Lilly insulin is almost 50 percent higher than [the] GPO [price]."[33] SNHPA asked HRSA to look into the matter, and HRSA provided no further response on this issue.

SNHPA members have also urged HRSA to address price adjustments and limited distribution to covered entities. In August 1999, for example, a SNHPA member hospital contacted HRSA, a distributor, and manufacturer regarding a rebate for an overpayment, and noted that no response was received as of January 20, 2000.[34]

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[29] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (Oct. 25, 2005).

[30] Email from Donna Evans, UAB Hospital Senior Pharmacist, to Ted Slafsky, SNHPA Executive Director (Oct. 10, 2005).

[31] Email from Ted Slafsky, SNHPA Executive Director, to HRSA (Oct. 10, 2005).

[32] Email from Jimmy Mitchell, HRSA OPA Director to Ted Slafsky, SNHPA Executive Director (Oct. 10, 2005).

[33] Email from Donna Evans, UAB Hospital Senior Pharmacist, to HRSA (Oct. 11, 2005).

[34] Facsimile from Mary Mazzara, Pharmacy Director, to Ted Slafsky, Executive Director, SNHPA (Jan. 20, 2000).

In addition, SNHPA itself has sought to direct HRSA's attention to the problem of manufacturer overcharges and to solicit a response from the agency. In 2000, concerned that the extent of 340B overcharges by manufacturers might be significant, SNHPA approached HRSA about performing a study that would track the various 340B prices paid by a group of hospitals over a one-year period, for a defined set of covered outpatient drugs.[35] SNHPA's plan was to provide HRSA with the results of the price comparison study, which HRSA would then review to determine if the hospitals in the study were overcharged and, if so, how much they were overcharged in the aggregate. By aggregating the overcharges, SNHPA reasoned, HRSA could avoid disclosing specific 340B ceiling prices, but could still provide a useful assessment of the scope of the problem. HRSA agreed to the request and, on December 1, 2000, SNHPA provided HRSA with prices on approximately 146 drugs purchased by six hospitals participating in the study.[36]

On January 22, 2001, HRSA responded by identifying 37 of the 146 drugs for which "significant" overcharges had occurred.[37] In a follow-up conversation with HRSA regarding the results of the government's analysis, SNHPA learned that the 37 drugs were sold at prices at least 10 percent higher than the statutory ceiling prices, and that many of the overcharges were in excess of 100 percent. According to HRSA,

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[35] Letter from William Von Oehsen, SNHPA Counsel, and Ted Slafsky, SNHPA Executive Director, to Jimmy Mitchell, Director, OPA (Dec. 1, 2000).

[36] Id.

[37] Letter from Jimmy Mitchell, Director, OPA, to William von Oehsen, SNHPA Counsel and Ted Slafsky, SNHPA Executive Director (Jan. 22, 2001).

several other drugs were overcharged but were not included in the list of 37, because the amount of the overcharge was less than 10 percent. Subsequent to this analysis, undertaken by HRSA itself, SNHPA repeatedly urged the agency, in meetings and via telephone, to take action to address the overcharge problems. HRSA did not do so.

As is reflected in the examples above, the voluntary dispute mechanism did not function to address the overcharge concerns of covered entities. In addition, due to lack of adequate staffing and resources, HRSA was often unable to provide responses to inquiries from 340B program participants or to take the initiative in addressing evidence of manufacturer overcharges.

3. *OIG And Congressional Pressure Failed*

The limitations of the 340B oversight mechanism raised concerns with both the OIG and Congress.

As is discussed in respondent's brief, a series of OIG reports, issued in March 2003 and June 2004, confirmed that drug manufacturers were overcharging 340B covered entities for drugs.[38] Respondent's Brief at 11-12. These reports further concluded that HRSA lacked the authority, information, and resources with which to prevent such overcharges. In the 2003 Report, entitled *Pharmaceutical Manufacturers Overcharged 340B Covered Entities*, the OIG estimated that five manufacturers had overcharged covered entities by a total of $6.1 million during the one-year period ending on September 30, 1999, for eleven prescription drugs. According to the 2003 Report, the overcharges occurred because the manufac-

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[38] 2003 Report at 4; OIG, *Appropriateness of 340B Drug Prices*, OEI-05-02-00070 (June 2004) ("2004 Report").

turers incorrectly excluded sales to HMO repackagers from their best price determinations. Because Medicaid rebates are calculated using formulas that are based upon a drug's "best price," the manufacturers, by omitting the reduced drug prices charged HMO repackagers, effectively excluded the lowest drug price from their total best price calculation. The Medicaid rebate amount was consequently miscalculated, based upon an inflated best price figure that excluded the repackager prices.[39]

This deception caused state Medicaid programs to overpay for drugs due to a reduced rebate amount, and also – as the 2003 Report concluded – resulted in overcharges to 340B covered entities. This was so because the formula used to determine 340B prices is based on the Medicaid drug rebate amount. When the calculation of "best price" and therefore the Medicaid rebate amount is incorrect, the calculation of the 340B discount will also be incorrect.[40] As a result, covered entities that purchased 340B drugs from HMO repackagers paid inflated prices for these drugs.[41]

In July 2004, in a follow-up to the 2003 and 2004 Reports that documented egregious manufacturer overcharges, Senator Charles Grassley, Chairman of the Committee on Finance, wrote to the Secretary and the HRSA Administrator. Senator Grassley requested that HHS disclose, among other things, its findings regarding the full extent of manufacturers' misreporting of best price, the full range of drugs that had been subject to repackager overcharges, the total overcharge for each covered entity, and the re-

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[39] 2003 Report at 3.

[40] Id. at 3.

[41] Id. at 4.

fund or credit plan that was developed for each covered entity affected by repackaging and the refund or credit recovered.[42]

In a response dated September 14, 2004, HRSA stated that the manufacturers involved in the repackaging schemes had been asked to determine the extent of the miscalculations of best prices and 340B prices for fiscal years including 1999, as well as the extent of overcharges for drugs that were not included in the 2003 survey.[43] According to HRSA, these manufacturers had also been asked to implement corrective action plans. HRSA also released names of four of the manufacturers involved in the repackaging schemes – Aventis, Bristol-Myers Squibb ("BMS"), GlaxoSmithKline ("GSK"), and TAP Pharmaceuticals.[44] HRSA discussed its proposed action plan and stressed the importance of implementing this plan before the agency would consider supporting any legislation or statutory changes that would increase HRSA's enforcement powers. HRSA also emphasized its view that the agency's compliance and enforcement tactics, and specifically its dispute resolution process, remained effective.[45]

Approximately one year later, having received no word from HRSA regarding the progress of its efforts to obtain information and cooperation from manufac-

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[42] Letter from Senator Charles E. Grassley, Chairman of the Committee on Finance, to The Honorable Tommy G. Thompson, HHS Secretary, and Dr. Elizabeth M. Duke, HRSA Administrator (July 23, 2004).

[43] "*HRSA Requests Refunds from Rx Manufacturers*," Federal Drug Discount and Compliance Monitor, Vol. 1, No. 5 (Nov. 2004), 1.

[44] Id.

[45] Id.

turers, Senator Grassley wrote to the HRSA Administrator again. Senator Grassley noted the following:

> In response to my letter of July 23, 2004, you stated that HRSA was sending letters to four drug companies – Aventis, Bristol-Myers Squibb, GSK, and TAP Pharmaceuticals – requesting that each develop "corrective action plans" for refunding or crediting the entities affected by the overcharges. It is my understanding that, with the exception of GSK's product Flonase, these companies have not issued refunds to 340B providers or indicated to HRSA that they intend to do so. Likewise, I understand that these companies have not followed through on HRSA's request to determine whether they overcharged 340B entities for other products.[46]

Senator Grassley was correct in his observations. In December 2005, as a result of growing concerns regarding deficiencies in the oversight of the 340B program, as highlighted by multiple OIG Reports addressing overcharge abuses by manufacturers,[47] the Subcommittee on Oversight and Investigations of the House Committee on Energy and Commerce held a hearing on "Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency." During this hearing, testimony was provided by the OIG regarding its concerns with

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[46] Letter from Senator Charles E. Grassley, Chairman of the Committee on Finance, to Dr. Elizabeth M. Duke, HRSA Administrator (Sept. 1, 2005).

[47] OIG, *Deficiencies in the Oversight of the 340B Drug Pricing Program*, OEI-05-02-00072, at 15 (Oct. 2005), http://oig.hhs.gov/oei/reports/oei-05-02-00072.pdf; 2003 Report.

340B program administration. An OIG representative testified that:

> Our work has led us to conclude that the 340B program may not be functioning as intended, which was to ensure that appropriate discounts on drugs are available to entities. Specifically, our work has found a number of deficiencies in program oversight as well as broader programmatic issues that impact HRSA's ability to administer the program.[48]

Testimony was also provided by HRSA. In one exchange, HRSA's Deputy Administrator underscored the absence of an effective administrative enforcement system:

> MS. DEGETTE. ...Now, according to the recent – the OIG report, even if your agency was able to accurately determine the drug manufacturers' ceiling prices, you wouldn't have the authority to enforce compliance to impose penalties, and so the OIG recommends that your agency seek legislation to give you that authority, including the ability to impose penalties. But in your response you said that HRSA does not want to establish penalties for violation. So my question is, how are you going to enforce compliance by drug manufacturers if there is no punishment for violations?
>
> MR. WILLIAMS. Well, this is a – we have one big penalty, which is to get them to leave the

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[48] *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency*, Hearing Before the Subcomm. on Oversight and Investigations of the H. Committee on Energy and Commerce, 109th Cong., H. Hrg. 109-108 (2006, http://www.gpo.gov/fdsys/pkg/CHRG-109hhrg30139/pdf/CHRG-109hhrg30139.pdf at 7 (testimony of Stuart Wright).

> Medicaid program or the 340B program. That's a very large penalty, which, as the IG correctly points out, the penalty is worse really than the problem we are trying to resolve.[49]

In a second exchange, the Deputy Administrator confirmed that HRSA had indeed been unsuccessful in obtaining manufacturer cooperation in resolving the repackager matters, and tacitly acknowledged that HRSA's dispute resolution process had never been utilized.[50]

In short, both Congress and the OIG identified serious shortcomings in HRSA's administrative enforcement of the 340B program and HRSA itself admitted these deficiencies. Yet none of this galvanized the agency to implement more effective administrative enforcement measures.

*4. The False Claims Act Has Been Of Very Limited Utility In 340B Cases*

Because of the lack of a non-voluntary dispute resolution mechanism with which HRSA could compel manufacturer refunds for overcharges, covered entities have been forced to go "outside" of the existing dispute mechanism in order to obtain relief from such overcharges. SNHPA, acting as liaison to the Department of Justice ("DOJ"), has sought to pursue restitution for a variety of manufacturer overcharges through False Claims Act ("FCA") settlements that resulted from manufacturers' overcharges to Medicaid. To that end, SNHPA conducted several meetings with DOJ and Assistant United States Attorneys, educating them about the link between the Medicaid rebate amount and 340B discounts. Unfortunately,

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[49] Id. at 33.

[50] Id. at 34-35.

despite SNHPA's urging, DOJ has never undertaken an action to address manufacturer overcharges on behalf of covered entities alone, and it is unclear whether the FCA can be invoked to recover a 340B overpayment. Regardless, covered entities have been limited to "piggybacking" on Medicaid rebate settlements in order to obtain relief.

Because they were not parties, however, covered entities were excluded from the actual Medicaid settlement negotiations, and the extent to which covered entity overcharges were addressed was therefore entirely within the discretion of government prosecutors. In some instances, covered entities were omitted entirely from the overcharge settlements with Medicaid, and, in other instances, they recovered relatively small amounts. For example, as noted in the Respondent's Brief at 9-10, following the disclosure of a repackager or "lick and stick" scheme by one whistleblower, petitioner Bayer settled federal FCA charges for $257 million and pled guilty to criminal charges in a Medicaid fraud settlement. $2.5 million of the settlement was awarded to 340B covered entities. A whistleblower suit also caused petitioner GSK to pay $87 million in restitution to Medicaid. Covered entities received approximately $9.4 million from this settlement. Petitioner BMS paid a settlement of $515 million to resolve allegations brought under the FCA, of which $124,000 was recovered by covered entities. Petitioner Aventis resolved consolidated FCA cases in a $95.5 million settlement, of which 340B entities recovered $7.3 million.

Again, the relatively small amounts received by covered entities as part of these Medicaid settlements were brokered by the DOJ and manufacturers

in negotiations that excluded covered entities. The disparity between the Medicaid and 340B reimbursement amounts thus raises questions as to whether the 340B settlements are reflective of actual overcharge amounts. Nonetheless, because of the limitations of the existing 340B dispute resolution process and oversight mechanism, covered entities were forced to accept the compensation provided under these agreements as their only available means of recovery, absent initiating litigation on their own behalf – the issue now before this Court.

* * * * *

The examples in this section represent but a sampling of the numerous instances in which the government has not responded to covered entity concerns or communications regarding manufacturer abuses, could not follow through with its own voluntary dispute resolution process, or was unable to compel manufacturer accountability in the face of evidence of manufacturer overcharges. Nevertheless, they underscore an obvious conclusion: the existing administrative mechanisms for addressing allegations of manufacturer overcharges were entirely inadequate, and HRSA, until now, has lacked the tools, resources, framework, and authority with which to protect covered entities adequately against manufacturer overcharges. The lack of a meaningful or effective oversight or dispute resolution mechanism has resulted in uncompensated overcharges that threaten to erode the ability of covered entities to carry out their mission of serving the nation's poor and most vulnerable.

## III. THE 340B REFORMS IN PPACA EVIDENCE CONGRESS'S KEEN AWARENESS THAT ADMINISTRATIVE ENFORCEMENT WAS SORELY LACKING

Given the tide of overwhelming discontent with the administrative enforcement of 340B requirements and OIG and congressional frustration with bureaucratic lassitude, it is unsurprising that Congress ultimately decided to make major changes to the 340B program in PPACA. The United States readily admits that PPACA "materially alters the 340B statutory framework by establishing a comprehensive administrative procedure to resolve claims by covered entities and to provide refunds and other remedies for violations." Brief for the United States at 10. It also notes that, although those reforms do not apply to the claims involved here, they will result in an "exclusive" administrative procedure in which claims related to the 340B program will then be "subject to judicial review pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §701 *et seq.*" *Id.* at 7 and 10.

In a failed attempt at intellectual legerdemain, however, the United States insists that this is further proof Congress has never intended that 340B entities be able to initiate private litigation to achieve enforcement. *Id.* at 10, 26, and 33. The Coalition believes that, to the contrary, the PPACA reforms underscore Congress's original determination that such actions were an integral and indispensable aspect of 340B enforcement. Indeed, Congress could well have concluded that, given the time and expense involved, the existence of contractual rights of action by financially hard-pressed 340B entities was not a

sufficient substitute for rigorous enforcement at the administrative level.

The changes made by PPACA to the 340B enforcement program are not mere tweaks to the prior system. Rather, they represent fundamental reforms and are an overt acknowledgment that the existing ***administrative*** enforcement system was both inadequate and unacceptable. Under Section 7102 to PPACA, entitled "Improvements to 340B Program Integrity," the Secretary must undertake extensive measures aimed at both manufacturer and covered entity compliance. 42 U.S.C. §256b(d)(1) and (2). With respect to drug manufacturers, these include:

- developing a system by which HHS may verify the accuracy of ceiling prices;
- establishing procedures for manufacturers to issue refunds to covered entities where there were overcharges;
- providing internet access for covered entities to the applicable ceiling prices;
- creating a mechanism for the reporting of subsequent rebates and other discounts and the appropriate crediting and refunding to covered entities;
- selective auditing of manufacturers and wholesalers; and
- imposing civil money penalties for overcharges.

Similar modifications are aimed at enabling HHS and drug manufacturers to monitor compliance by covered entities with 340B requirements. *Id.* at §256b(d)(2).

Additionally, the Secretary is required to issue regulations that establish and implement an administrative process to resolve claims by covered entities

as to overcharges and claims by manufacturers as to non-compliance by covered entities. *Id.* at §256b(d)(3)(A). These procedures must include remedies and enforcement of the determinations as well as deadlines and mechanisms for litigating these claims administratively. *Id.* at §256b(3)(A) and (B). Notably, Congress specified that:

> The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a ***formal agency decision*** and shall be ***binding*** upon the parties involved, unless ***invalidated by an order of court of competent jurisdiction***.

*Id.* at §256b(d)(3)(C) (emphasis added). In other words, as the United States has conceded, Congress not only directed that there be a meaningful administrative forum for 340B claims but also specifically provided for judicial review of those administrative determinations. Brief for the United States at 7.

On September 20, 2010, HHS issued advanced notice of proposed rulemaking and requested comments concerning how it should devise such an administrative process.[51] 75 Fed. Reg. 57233. In this notice, HHS admitted that, prior to PPACA, HRSA did not have a required administrative dispute resolution process and, in a notable understatement, acknowl-

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[51] Under Section 7102(a) of PPACA, 42 U.S.C. §256b(d)(3)(A), the Secretary was to publish administrative dispute resolution regulations for 340B within 180 days of enactment. Because the Secretary missed this deadline, it is not possible at this juncture to define the exact parameters of that process but, presumably, it will be mandatory, establish a meaningful process to adjudicate claims, and allow for judicial review of final agency determinations.

edged that its prior process had been underutilized. *Id.* at 57233, 57234.

At bottom, petitioners and the United States basically contend that, prior to PPACA, there was neither transparency nor accountability in the 340B program and that Congress deliberately constructed it that way. To the contrary, as the Ninth Circuit recognized, Congress specifically directed the use of PPAs where 340B covered entities would be third party beneficiaries and, as such, could vindicate their rights pursuant to suits seeking contractual remedies. To hold otherwise is to accept the notion that Congress was consciously indifferent to the lack of administrative enforcement of 340B requirements and intent on ensuring the unavailability of program-related remedies. Such a notion does not square with PPACA's 340B reforms. More importantly, in the context of this case, it does not accord with the fact that Congress expressly directed that contractual arrangements be utilized as a vehicle for imposing statutory requirements on manufacturers. As an intended beneficiary of those PPA contracts, the respondent is entitled to sue to seek relief for their breach to vindicate its rights as well as to safeguard the medical needs of its patients and the financial interests of the taxpayers underwriting the costs of indigent care.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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December 20, 2010

# AMICUS CURIAE BRIEF

No. 09-1273

IN THE

# Supreme Court of the United States

ASTRA USA, INC., et al.,

*Petitioners,*

*v.*

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

*Respondent.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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**Cases:**

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*County of Santa Clara v. Astra USA Inc.*,
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*Dutton v. Poole*,
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*Empire HealthChoice Assur., Inc. v. McVeigh*,
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*German Alliance Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220 (1912) ..... 25

*H.R. Moch Co. v. Rensselaer Water Co.*,
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*Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union, AFL-CIO-CLC*, 457 U.S. 15 (1982) ..... 23

*Lawrence v. Fox*,
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*Martinez v. Socoma Cos.*,
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*Cited Authorities*

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*Martyn v. Hind*,
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*Robins Dry Dock & Repair Co. v. Flint*,
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*Samantar v. Yousuf*,
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*Schemerhorn v. Vanderheyden*,
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*Sec. Mut. Casualty Co. v. Pacura*,
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*Starkey v. Mill*,
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*United States v. Seckinger*,
397 U.S. 203 (1970) ..... 2, 22

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**Statutes & Other Authorities:**

42 U.S.C. § 256b(a)(1) ..... 1, 20, 23

42 U.S.C. § 256b ..... 20

42 U.S.C. § 256b ..... 4

42 U.S.C. § 256b(a)(5)(D) ..... 25

58 Fed. Reg. 27289 ..... 25

3 E. Allan Farnsworth, *Farnsworth on Contracts* (3d ed. 2004) ..... 3, 19

Melvin A. Eisenberg, *The Nature of the Common Law* 50 (1988) ..... 14

Melvin Aron Eisenberg, Third-Party Beneficiaries, 92 Colum. L. Rev. 1358 (1992) *passim* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 .. 21

Peter Karsten, *"Discovery" of Law by English and American Jurists of the Seventeenth, Eighteenth, and Nineteenth Centuries: Third-Party Beneficiary Contracts as a Test Case*, 9 Law & Hist. Rev. 327 (1991) ..... 4, 5

R. Fallon *et al.*, *Hart and Wechsler's The Federal Courts and the Federal System* 700 (5th ed. 2003) ..... 2

*Cited Authorities*


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| Restatement of the Law, Contracts, § 133 ..... | 7, 8 |
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## INTEREST OF *AMICI CURIAE*[1]

*Amici* are professors who teach and research American contract law. This case raises a question about the federal common law of contracts, and our scholarly aim is to advise the Court on principles of American contract law.

We file this brief as individuals and do not speak for our institutions.

## INTRODUCTION AND SUMMARY OF ARGUMENT

This case implicates a question of contract law: when may those who are not parties to a contract enforce it?

The contract in this case (the "Pharmaceutical Pricing Agreement," or "Agreement") is a agreement between Petitioners and the Secretary of Health and Human Services. Under the agreement, Petitioners must offer certain drugs to parties like the Respondent ("Covered Entities") under a particular pricing scheme. Section 340B of the Public Heath Service Act, 42 U.S.C 256b(a)(1), required the Secretary to enter into the Agreement.

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1. No counsel for a party authored this brief in whole or in part, and none of the parties or their counsel, nor any other person or entity other than *amici*, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amici* represents that all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amicus* briefs have been filed with the Clerk.

The Agreement, under its terms and this Court's jurisprudence, is enforceable in federal courts under federal contract law. *See* Agreement ¶ VII(g); *United States v. Seckinger*, 397 U.S. 203, 209–210 (1970) ("[F]ederal law controls the interpretation of the contract. This conclusion results from the fact that the contract was entered into pursuant to authority conferred by federal statute and, ultimately, by the Constitution.") (citations omitted).[2] Federal courts appropriately look to American common-law principles for guidance in fashioning federal common law. *Seckinger*, 397 U.S. at 210 ("In fashioning a federal rule we are, of course, guided by the general principles that have evolved concerning the interpretation of contractual provisions . . . .").

Accordingly, this brief explains how American contract law distinguishes beneficiaries that can enforce a contract from those that cannot. Courts use a variety of principles, and sometimes it is often surprisingly difficult to determine the precise conditions under which third parties should be able to enforce contracts. This case, however, is not a difficult one as a matter of contract law; contract principles permit the Covered Entities to enforce the Agreement at issue in this case.

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2. This brief does not address what the opinion below called the "famously obscure" question of "whether federal or state law creates the cause of action underlying [Respondent's] claim." *County of Santa Clara v. Astra USA Inc.*, 588 F.3d 1237, 1244 n. 5 (9th Cir. 2009). Nor does it address this Court's holding that "'uniform federal law need not be applied to all questions in federal government litigation, even in cases involving government contracts.'" *Empire HealthChoice Assur., Inc. v. McVeigh*, 547 U.S. 677, 691 (2006) (quoting R. Fallon et al., *Hart and Wechsler's The Federal Courts and the Federal System* 700 (5th ed. 2003)).

## ARGUMENT

### I. THE COMMON LAW PERMITS "INTENDED" THIRD-PARTY BENEFICIARIES TO ENFORCE CONTRACTS

Under American contract law, it is an uncontroversial proposition that those who are not parties to a contract may sometimes enforce its terms, even when the contract does not explicitly address the question of whether they should be permitted to do so. *See* Restatement of the Law, Second, Contracts § 304 ("A promise in a contract creates a duty in the promisor to any intended beneficiary to perform the promise, and the intended beneficiary may enforce the duty.") (1981) [hereinafter "*Second Restatement*"]; Restatement of the Law, Contracts, ch. 6 (entitled "Contractual Rights Of Persons Not Parties To The Contract") (1932) [hereinafter "*First Restatement*"]; 3 E. Allan Farnsworth, *Farnsworth on Contracts* §§ 10.2, 10.3 (3d ed. 2004).

Of course, not everyone who seeks to enforce a contract may do so. It is often said that only "intended beneficiaries" of a contract, as opposed to its "incidental beneficiaries," may enforce it. *See Second Restatement* §§ 302, 304. The phrases "intended beneficiary" and "incidental beneficiary," however, often merely state conclusions; parties that are permitted to enforce a contract are said to be intended beneficiaries, and those that are not are said to be incidental beneficiaries. This Part develops the history and doctrinal analysis behind those conclusions.

## A. The Common Law Has Long Permitted Third-Party Beneficiaries to Enforce Contracts

1. Third-party enforcement of contracts is not a new phenomenon. Indeed, the principle that many third parties could enforce contracts without explicit authorization to do so was relatively uncontroversial in the early law of the United States and in the English law from which U.S. law was derived. The early cases did not articulate clear principles about which third-party beneficiaries could enforce contracts and which could not, but even at early common law there was no conceptualistic assumption that only parties to contracts could enforce them. To put it differently, for hundreds of years the existence of an "agreement" or a "contract," as called for by Section 340B, 42 U.S.C. § 256b, has connoted the possibility of third-party enforcement.[3]

English *assumpsit* cases as early as the mid-1600s held that nonparties could enforce promises.[4] *Dutton v.*

3. For a history of the early English and American cases governing third-party beneficiaries, see Peter Karsten, *"Discovery" of Law by English and American Jurists of the Seventeenth, Eighteenth, and Nineteenth Centuries: Third-Party Beneficiary Contracts as a Test Case*, 9 Law & Hist. Rev. 327 (1991); *see also* Melvin Aron Eisenberg, Third-Party Beneficiaries, 92 Colum. L. Rev. 1358 (1992). This brief's examples of historical cases come from Professor Karsten's and Professor Eisenberg's articles.

4. *See Starkey v. Mill*, 82. Eng. Rep. 723 (K.B. 1651) ("[T]he goods were given for the benefit of the plaintif, though the contract be not between him and the defendant, and he may well have an action . . ., for here is a promise in law made to the plaintif, though there be not a promise in fact, & there is a debt here; and the assumpsit is good.").

*Poole*, 83 Eng. Rep. 523 (K.B. 1677), is representative of the early case law. In *Dutton*, a son and heir promised his father that he would pay his sister £1000; in exchange, the father agreed not to sell a piece of property he owned in order to raise money for his younger children. The court held that the sister could enforce the contract.

*Dutton* was not unique, and its doctrinal soundness was well established in English law by 1776, at which time Lord Mansfield, addressing a potential issue concerning the law of third-party beneficiaries, mused that "it is a matter of surprise, how a doubt could have arisen" in *Dutton*. *Martyn v. Hind*, 98 Eng. Rep 1174 (K.B. 1776).

Following the English cases, early American law similarly allowed third parties to enforce contracts without significant controversy. *See* Karsten, *supra* note 3, at 340; Eisenberg, *supra* note 3, at 1362–1365. In 1806, a New York court articulated its view of the doctrinal principle behind the cases as follows: "[W]here one person makes a promise to another for the benefit of a third person, that third person may maintain an action on such promise." *Schemerhorn v. Vanderheyden*, 1 Johns. 139, 140 (N.Y. Sup. Ct. 1806). *Schemerhorn* added that "The same principle has, since [*Dutton*], been repeatedly sanctioned by the decisions of the English courts." *Id.* According to Professor Karsten, "between 1801 and 1820 the high courts of the first four American jurisdictions to address the problem spoke as one." Karsten, *supra*, at 340.

Representative of the early American rule is the well-known case of *Lawrence v. Fox*, 20 N.Y. 268 (1859),

although it is incorrect to think that *Lawrence* was either novel or particularly influential in its time. *See* Eisenberg, *supra* note 3, at 1363. In *Lawrence*, Fox had borrowed $300 from Holly, promising Holly that he would pay it to Lawrence (to discharge a debt from Holly to Lawrence). The court held that Lawrence could enforce the contract between Holly and Fox even though Lawrence was not a party. *Lawrence*, 20 N.Y. at 269.

2. *Lawrence*, far from heralding the start of third-party enforcement of contracts in the United States, as is sometimes supposed, did signal a temporary retrenchment. The *Lawrence* court was deeply divided, and as Professor Melvin Eisenberg, a leading contracts scholar, has observed, "what is striking about *Lawrence v. Fox* is not how far it advanced the law, which was very little, but how this now-celebrated case was almost drowned by the rising tide of classical contract law only ten or fifteen years after it was decided." Eisenberg, *supra* note 3, at 1363.

What Professor Eisenberg calls "classical contract law" was the conceptualistic, axiomatic approach to deciding contract cases that was prominent in the late 1800s and early 1900s. *See id.* at 1365. During that period, in both England and the United States, concerns about the lack of privity (or occasionally lack of consideration) between contracting parties and third parties led courts to question or even overturn the result in *Dutton*. *See id.* at 1365–71. These concerns were essentially circular: nonparties could not enforce contracts, courts began to hold, because only a party to a contract could have rights under it. *Cf. id.* at 1370. No justification for a rule based on that principle, or for a change in the doctrine, was offered.

The attempt to reason purely axiomatically about contract law did not last far into the 1900s. *See generally* Eisenberg, *supra* note 3, at 1371–74. It was well eclipsed by the time Section 340B of the Public Health Service Act was passed in 1992.

3. Indeed, even the *First Restatement*, conceptualistic in other areas, did not adopt a restrictive view of third-party beneficiaries. The *First Restatement* specified that two categories of third-party beneficiaries could enforce contracts: "donee beneficiaries," like the plaintiff in *Dutton* on whom one or both of the parties meant to confer a gift, and "creditor beneficiaries," like the plaintiff in *Lawrence* to whom one of the parties owed a debt. *First Restatement* § 133.

The *First Restatement* defined the terms as follows:

> [A beneficiary is] a donee beneficiary if it appears from the terms of the promise in view of the accompanying circumstances that the purpose of the promisee in obtaining the promise of all or part of the performance thereof is to make a gift to the beneficiary or to confer up on him a right against the promisor to some performance neither due nor supposed or asserted to be due from the promisee to the beneficiary
>
> [A beneficiary is] a creditor beneficiary if no purpose to make a gift appears from the terms of the promise in view of the accompanying circumstances and performance of the promise will satisfy an

> actual or supposed or asserted duty of the promisee to the beneficiary, or a right of the beneficiary against the promisee which has been barred the statute of Limitations or by a discharge in bankruptcy, or which is unenforceable because of the Statute of Frauds.

*Id.* Those who benefit from a contract but are neither donee beneficiaries nor creditor beneficiaries—and thus without a right to enforce it—are called "incidental beneficiaries." *Id.* § 133(1)(c).

Two features of the *First Restatement* rule are worth highlighting. First, the tests depend on the purposes that are inferred from the "terms of the promise in view of the accompanying circumstances." The inquiry is necessarily purposive and contextual, and even though the *First Restatement* is not known for open-ended inquiries generally, it does not restrict the purposive inquiry to limited sets of evidence such as the text of the contract. *See* Eisenberg, *supra* note 3, at 1376; Samuel Williston & George J. Thompson, *A Treatise on the Law of Contracts* § 356A, at 331 (rev. ed. 1938).

Second, under the *First Restatement*, "donee" beneficiaries are not necessarily those to whom the promisor or promisee intended to confer a *gift*. *See* Eisenberg, *supra* note 3 at 1376. The category also includes those who, even though they are not receiving a gift or donation, are inferred to have "a right against the promisor" in view of the "purpose of the promisee." *First Restatement* § 133(1)(a). Precisely what this means is unclear because the *First Restatement*, as Professor

Eisenberg has put it, "provided no guidance concerning the critical question of how a court was to determine whether the relevant purpose was present." Eisenberg, *supra* note 3, at 1377.

To interpret the *First Restatement*'s test generously, it is possible that it makes some easy cases easy, but that is probably the best it can do. Contracts clearly intended to confer a gift or discharge a debt lead, fairly simply under the *First Restatement*'s test, to third-party enforcement rights. Unfortunately, other cases are more difficult, and the *First Restatement* provides little guidance as to those cases.

4. The *Second Restatement* is probably the most widely used summary of modern black-letter contract law. It abandons the *First Restatement*'s "donee beneficiary" and "creditor beneficiary" categories, at least in name:

> (1) Unless otherwise agreed between promisor and promisee, a beneficiary of a promise is an intended beneficiary if recognition of a right to performance in the beneficiary is appropriate to effectuate the intention of the parties and either
>
> > (a) the performance of the promise will satisfy an obligation of the promisee to pay money to the beneficiary; or
> >
> > (b) the circumstances indicate that the promisee intends to give the

> beneficiary the benefit of the promised performance.
>
> (2) An incidental beneficiary is a beneficiary who is not an intended beneficiary.

*Second Restatement* § 302.

Note, as with the *First Restatement*, that the inquiry is purposive and contextual, and third-party enforcement does not depend on explicit authorization in the contract's text.

Despite their terminological differences, it is not clear that the tests of the *First Restatement* and the *Second Restatement* are, in practice, very different from each other. Paragraph 302(1)(a) of the *Second Restatement* might be taken to apply to the *First Restatement*'s creditor beneficiaries, and paragraph 302(1)(b) might be taken to apply to the *First Restatement*'s donee beneficiaries. *Cf.* Eisenberg, *supra* note 3, at 1382.

What the *Second Restatement* adds, at least overtly and as a matter of doctrinal emphasis, is a dependence on the "intention" of the parties. As the introductory clause to *Second Restatement* § 302 suggests, modern courts often focus on whether a third party is an "intended" beneficiary of a contract in deciding whether to permit that party to enforce the contract. This is often true even of courts that use the test of the *First Restatement* rather than that of the *Second Restatement*. For a list and discussion of cases applying

intent-to-benefit tests, see Eisenberg, *supra* note 3, at 1378–81.[5]

What "intent" means in this context, however, is often not clear. As Professor Eisenberg points out, the word "intent" is often ambiguous between subjective intent and objectively manifested intent, on one hand, and between narrow intents and broader purposes, on the other. *Id.* at 1378. As a result, it is often unclear how to apply the test. *Id.* at 1379–81.

For example, if the test refers to objectively manifested intent, it provides very little guidance in resolving questions about which third-party beneficiaries should be able to enforce contracts: "How is it to be determined, as an objective matter, why in some contracts whose performance will benefit a third party, the benefit is objectively 'intended' within the meaning of the test, while in other contracts whose performance will benefit a third party, the benefit is not so 'intended'?" *Id.* at 1379.

Some courts have attempted to address the ambiguities in intent-based tests by imposing additional requirements before allowing third parties to enforce

5. It should not be a surprise that even courts that purport to apply the test of the *First Restatement* use an intent-based test. Recall that *First Restatement* allows a class of donee beneficiaries to enforce contracts when "the purpose of the promisee in obtaining the promise . . . is to . . . confer upon [the beneficiary] a right against the promisor." *First Restatement* § 133(1)(a). Accordingly, even that test relied largely on the "purpose" of the contracting parties, which in this context appears to mean roughly the same thing as "intent."

contracts. For example, some courts purport to apply a test that requires the intent to benefit third parties to be "clear" or "definite." *E.g.*, *Sec. Mut. Casualty Co. v. Pacura*, 402 So. 2d 1266, 1267 (Fla. Dist. Ct. App. 1981) (holding that third parties may enforce contracts "where the provisions of the contract clearly show an intention primarily and directly to benefit the individual bringing suit or to a class of persons to which he claims to belong as a third party beneficiary"). Others require that contracts expressly confer a right to enforce the agreement on third parties. Professor Eisenberg responds nicely to these additional requirements, however:

> Both types of requirement are inconsistent with modern principles of contract interpretation, which do not place a thumb on the interpretative scale and do allow courts to look to surrounding circumstances. And both types of requirement are difficult or impossible to apply meaningfully and consistently, and are not so applied in fact. The better-reasoned cases reject these formal requirements, and so does [the *Second Restatement*].

Eisenberg, *supra* note 3, at 1379–80.

5. *A synthesis.* Professor Eisenberg's comprehensive article concludes that the most justifiable legal rule permits third-party beneficiaries to enforce contracts where either:

> (I) allowing the beneficiary to enforce the contract is a necessary or important means of effectuating the contracting parties' performance objectives, as manifested in the contract read in the light of surrounding circumstances; or
>
> (II) allowing the beneficiary to enforce the contract is supported by reasons of policy or morality independent of contract law and would not conflict with the contracting parties' performance objectives.

Eisenberg, *supra* note 3, at 1385.

Professor Eisenberg's synthesis ordinarily suggests an inquiry into the circumstances of the parties' bargaining. Of course, not all contracts cases reflect true bargains; the Agreement at issue in this case was not the product of a bargain, for example. But the lack of a bargain does not generally render contracts unenforceable; it merely changes the inquiry from one about actual bargains to one about whether a form's terms are reasonable and about whether parties would have nonetheless assented to a contract knowing that it contained particular terms. *See* Second Restatement § 211.

Incidentally, it is important to note that the second part of Professor Eisenberg's test explicitly incorporates the kinds of moral and policy propositions that justify the common law of contracts. *See id.* at 1358–1359. Modern American contract law explicitly incorporates such propositions as justifications, and it

is difficult to understand or apply modern contract law without recognizing and evaluating those propositions. *See generally* Melvin A. Eisenberg, *The Nature of the Common Law* 50–76 (1988).

### B. Similar Substantive Principles Apply to Private Contracts and Government Contracts, Particularly Where Third-Party Beneficiaries Seek General Damages, Not Consequential Damages

1. Under the law governing third-party beneficiaries, government contracts tend to present at least some factual differences from private contracts.

One difference is that when a governmental entity is a party to a contract, parties outside the government will almost necessarily benefit from it, at least indirectly. *See Second Restatement* § 313 cmt. a. ("Government contracts often benefit the public . . . ."). Many individuals have no recognizable dependents and enter into contracts only or largely for themselves, but organizations like governments typically act, at least in principle, for the benefit of others.

Moreover, government contracts potentially have large numbers of beneficiaries; it is easier for the government to affect many parties than for most individuals to do so. *See* Eisenberg, *supra* note 3, at 1407.

Perhaps for these reasons, courts have been careful when identifying intended beneficiaries of government contracts, and they have often constructed nominally different principles to guide that identification.

For example, the *Second Restatement* includes a special rule for government contracts, laid out in section 313. On the surface, the section has two separate roles. First, it makes clear that the interpretation of government contracts is subordinate to, and must be consistent with, the "policy of the law authorizing the contract or prescribing remedies for its breach." *Second Restatement* § 313(1). Second, it purports to restrict the circumstances under which third-party beneficiaries may recover "consequential damages" under a government contract. *Id.* § 313(2).

For several reasons, however, it is unclear whether section 313 of the *Second Restatement* presents a rule that differs substantively from the Restatement's more general principles. Section 313(1), to the extent it simply subordinates contract interpretation to statutory policy, is probably uncontroversial, but a similar principle applies to the relationship between public laws and *private* contracts: a constitutionally valid statute may expand or restrict remedies for private contracts just as it could for governmental contracts, and indeed it might do so on matters far broader than questions of third-party enforcement. Section 313(1), therefore, essentially states the truism that properly enacted statutes can change parties' legal rights.

Nor is it clear that section 313(2) departs significantly from more general principles of third-party enforcement.[6] For one thing, it applies only to

6. Professor Eisenberg believes it may. See Eisenberg, *supra*, at 1407 n. 170. But as he observes, "Section 313 is not a model of clarity." In any event, his argument is that there is no *reason* to treat government contracts in a manner categorically

(Cont'd)

consequential damages, and third-party enforcement for consequential damages is likely comparatively rare; for example, consequential damages do not figure at all in the remedies Respondent seeks in this case. Even where third parties seek to receive consequential damages under a contract, however, section 313(2) may be consistent with the Restatement's more general rule: it appears simply to allow consequential damages when either (1) the contract explicitly permits them or (2) the contract impliedly permits them.

In short, it is unclear that section 313 substantively departs from the Restatement's general principles that govern private contracts. Indeed, the Restatement itself purports not to, observing in a comment that section 313(2) "applies to a particular class of contracts the classification of beneficiaries in § 302." *Id.* § 313 cmt. a.

2. Further discussion of the difference between general damages and consequential damages may be helpful. The terms do not have rigid meanings, but general damages are those that a promisee can recover for "loss that results in the ordinary course of events," whereas consequential damages are those "recoverable for loss that results other than in the ordinary course of events." *Second Restatement* § 351 cmt. b. As perhaps a more useful distinction, general damages reflect damages that essentially any promisee would receive, such as the difference between a promised price for a

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(Cont'd)

different from private contracts. *Id.* at 1407. That is, he believes that even if section 313(2) does vary from contract law's general principles, that variation would be a mistake.

commodity and a price that a promisee must pay when the contract is breached; consequential damages, by contrast, result from harms that are more particular to the individual promisee.

For instance, because Respondent seeks to recover from Petitioners the difference between the prices for covered drugs to which the Agreement entitled them and the prices they were in fact charged for covered drugs, they are seeking a paradigmatic example of general damages. If, hypothetically, they sought damages for a problem in medical treatment that arose because drugs were not available at the Agreement's guaranteed price, those damages would be consequential.

Where expanding the range of parties that can recover consequential damages may vastly increase the promisor's total liability under a contract, courts have been reluctant to permit third parties to enforce contracts—particularly government contracts. The famous case of *H.R. Moch Co. v. Rensselaer Water Co.*, 159 N.E. 896 (N.Y. 1928) (Cardozo, J.) is illustrative. In *Moch*, a water supplier breached its contract to supply water to a city, but it was not liable to a third party for fire damage that resulted from its breach.

Ordinarily, promisors, like Petitioners in this case, can more easily predict general damages than consequential damages; allowing third parties to receive general damages does not ordinarily threaten limitless or unmanageable liability. Accordingly, there is less reason to scrutinize the third-party beneficiaries of government contracts when those beneficiaries seek

only general damages. The danger of limitless liability, or even merely increased liability, is minimal when third parties seek general damages. Those damages are easy to predict, could have been due to the promisee anyway, and are not significantly expanded by permitting third parties to enforce contracts.[7]

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7. Compare the *First Restatement*'s approach to government contracts. The *First Restatement* does not treat government contracts differently in general, as if they were a separate class of contracts, but it does attempt to limit what appear to be consequential damages to members of the public. Specifically, the *First Restatement* aims to prevent some parties who promise governments "to do an act or render a service" from liability for "compensation for the injurious consequences of performing or attempting to perform" the service. *First Restatement* § 145. The focus is on "compensation for the injurious *consequences*" (emphasis added), not for market damages from breach of contract.

Perhaps oddly, the *First Restatement* indicates that even this limitation on consequential damages should not apply to cases where the promisor has contracted with a municipality (and apparently only a municipality) "to render services the non-performance of which would subject the municipality to a duty to pay damages." *Id.* § 145(b). The *First Restatement* does not make the motivation for this exception clear, but the illustrations suggest that section 145 means to prevent liability for consequential damages, as in *Moch*, but to allow damages for more direct harms, such as when a contractor promises to keep a municipality's streets safe and fails to do so, injuring a member of the public. *See id.* cmt. a. illus. 2, 5. An easier way to reach the same result is to say that in the latter case, the contractor could easily have foreseen that its breach of contract could lead to the kinds of damages it caused.

In short, general damages like those at issue in this case do not significantly change the legal duties or the total amount of liability that promisors like Petitioners face. As a result, there is little fear here of the dangers with which Cardozo was concerned in *Moch*. *Accord* Farnsworth, *supra*, § 10.6 ("[I]f consequential damages are not involved, so that the promisor's risk is more limited, as when the contract merely fixes a maximum rate for a utility company, courts have permitted enforcement by third persons."); *cf.* Eisenberg, *supra* note 3, at 1409 n. 176 (suggesting that "if not for the problem of extended liability," the decision to permit "a well-defined and specifically favored class" of third parties to enforce a government contract would be straightforward).

## II. PRINCIPLES OF AMERICAN CONTRACT LAW PERMIT THE COVERED ENTITIES TO ENFORCE THE PHARMACEUTICAL PRICING AGREEMENT

As Part I demonstrated, American contract law permits third-party enforcement for many contracts, but it does not offer singular or reductive rules by which courts can easily address questions concerning third-party enforcement. Although inconsistencies among cases might be problematic in many third-party-beneficiary cases, however, Respondent's case is relatively straightforward as a matter of contract law; under essentially every contract-law test that courts have applied, the Covered Entities may enforce the Agreement. This section lays out further details of various doctrinal approaches and applies them to the Covered Entities' case.

1. *A review of the contract and its authorizing statute.* The Agreement, as noted at the outset, is a agreement between the Department of Health and Human Services and Petitioners, called for by section 340B of the Public Health Service Act, 42 U.S.C. § 256b. The statute requires the Secretary to enter "an agreement" with manufacturers "under which the amount required to be paid . . . to the manufacturer for covered outpatient drugs" is set so that it "does not exceed" a ceiling price computed under the statute. 42 U.S.C. § 256b(a)(1)

The most significant agreement of the Agreement is set out in paragraph II, under which Petitioners agreed as follows:

> for single source and innovator multiple source drugs, to charge covered entities a price for each unit of the drug that does not exceed an amount equal to the AMP for the covered outpatient drug reported (or which would have been reported had the Manufacturer participated in the Medicaid rebate program) to the Secretary in accordance with the Manufacturer's responsibilities under section 1927(b)(3) of the Social Security Act, reduced by the rebate percentage.

Agreement ¶ II(a). That Paragraph, in order to achieve the objectives of section 340B, imposes on Petitioners a separate *contractual* obligation to charge 340B entities based on AMPs and best prices reported in accordance with their responsibilities under the Medicaid rebate statute.

The Agreement also provides an "elective dispute resolution process," *id.* ¶ IV, that gives Petitioners and the Secretary various rights. It is not a comprehensive or binding dispute-resolution procedure, however, as the Agreement explicitly notes: "Nothing in this paragraph shall preclude [Petitioners] or the Secretary from exercising such other remedies as may be available by law."[8]

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8. Of course, the paragraph does not explicitly retain rights for third parties, but it had no reason to do so because it did not grant extra rights to third parties. Indeed, paragraph IV as a whole strongly suggests that the Agreement conceived of flexible rather than narrow dispute-resolution procedures.

Had the Agreement provided a comprehensive and mandatory dispute-resolution procedure that referred only to the parties, contract principles would likely oppose third-party enforcement. *See Martinez v. Socoma Cos.*, 11 Cal. 3d 394 (Cal. 1974) (holding that third parties could not enforce a federal-government contract because "the contracts' provisions for retaining the Government's control over determination of contractual disputes and for limiting defendants' financial risks indicate a governmental purpose to exclude the direct rights against defendants claimed here"). But the Agreement's dispute-resolution procedures are explicitly not mandatory. *Contra* Brief for APA Watch as *Amicus Curiae* Supporting Petitioners 9 ("[*E*]*ven the United States* could not enforce the Agreement under contract law, without first invoking the Agreement's dispute-resolution provisions." (italics in original)).

It is beyond the scope of this brief to analyze the changes to relevant dispute-resolution procedures that will be made in the future under the Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119.

2. *Application of contract-law principles to the Agreement.* Contract principles permit Covered Entities like Respondent to enforce the Agreement. Indeed, as a matter solely of contract principles, this case is a straightforward one.

As a preliminary matter, we see no reason not to treat the Agreement as a contract. *See Second Restatement* § 1 (defining contracts). It is true, as the United States observes, that the Agreement does not arise from an individually negotiated transaction. *See* Brief for the United States as Amicus Curiae Supporting Petitioners 15–19. But the absence of individual negotiation does not make a contract unenforceable. *See Second Restatement* § 211. A statute's determination to achieve a result by means of contractual agreement implicates contract law; indeed, "where a common-law principle is well established . . . the courts may take it as given that Congress has legislated with an expectation that the principle will apply." *Astoria Fed. Sav. & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991).[9]

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9. The principle that the federal common law of contracts applies to government contracts is well established. *See, e.g., Seckinger*, 397 U.S. at 209–210.

The Washington Legal Foundation, as *amicus curiae* in support of Petitioners, would require even narrow legal propositions—like the availability of third-party enforcement for federal contracts called for by statutes—to be "well-established" even where they are simply instances of settled common-law principles. *See* Brief of Washington Legal Foundation as *Amicus Curiae* in Support of Petitioners 12 ("[T]here is no well-established federal common law rule permitting suits by intended beneficiaries under contracts of this sort (*i.e.*, contracts mandated by a federal statute and (Cont'd)

Although, as Petitioners note, "an agency cannot by regulation create a cause of action to enforce a statute," Pet. Br. at 15, an agency must surely enter into an enforceable contract where a statute directs it to do so.[10]

Several features of the contract in this case are clear. A significant performance objective of the contract is clearly to limit the price that Covered Entities must pay Petitioners for particular drugs. Section 340B requires specifically that an agreement be made to prevent prices from exceeding a particular computed amount; the Agreement fulfills that requirement. The contracts and the statute behind them seek to provide Covered

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(Cont'd)
intended to ensure compliance with a statutory requirement)."). But their position is mistaken. *See Samantar v. Yousuf*, 130 S. Ct. 2278, 2290 n.13 (2010) (quoting *Astoria*, 501 U.S. at 108, for the proposition that "Congress 'is understood to legislate against a background of common-law . . . principles'" (ellipsis in original)). In any event, it would be unusual for a narrow principle to be as thoroughly settled as the Washington Legal Foundation appears to demand.

10. This brief does not take a position on the general federal jurisprudence concerning implied statutory private rights of action, except to note that questions about the private rights implied by a statute are analytically distinct from questions about claims for breaches of contracts that have been authorized or required by a statute, and therefore would appear to be inapplicable here *See Jackson Transit Auth. v. Local Div. 1285, Amalgamated Transit Union, AFL-CIO-CLC*, 457 U.S. 15 ("[O]n several occasions the Court has determined that a plaintiff stated a federal claim when he sued to vindicate contractual rights set forth by federal statutes, despite the fact that the relevant statutes lacked express provisions creating federal causes of action.").

Entities with drugs under a particular pricing scheme, and neither the contract nor the statute channels or limits remedies in ways that suggest third-party enforcement is inconsistent with the performance objectives of the contract. Importantly, because the Covered Entities seek only general market damages, Petitioners' potential liability under the contract would not increase because of third-party enforcement.[11]

Under the *First Restatement* test, the Covered Entities are a well-defined group of true donee beneficiaries who are seeking nonconsequential damages. Under the *Second Restatement* test, Covered Entities clearly are intended to benefit from the contract, in view both of its text and its fulfillment of the obligations of a statute one of whose chief purposes was to ensure that they receive drugs under a particular pricing scheme.

3. *Application of narrower doctrinal tests.* Occasionally, courts allow beneficiaries to enforce contracts if (and only if) the contract has called for

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11. That is, Petitioners would need to pay only those damages they might have owed had the Department of Health and Human Services enforced the Agreement.

Of course, Petitioners may face lawsuits from a greater number of parties if third-party enforcement is permitted, and they may need to disclose information in those lawsuits that they would not have needed to disclose otherwise, as the United States argues. *See* Brief for the United States as *Amicus Curiae* Supporting Petitioners 28–29. But there is no indication they would have refused to sign the Agreement if third-party enforcement had been explicit, nor is there any indication of a direct conflict between third-party enforcement and the Medicaid Act. *Contra id.* at 28.

performance to be provided *directly* to the beneficiaries.[12] Directness of performance is a questionable criterion in determining the appropriateness of third-party enforcement under modern contract law. *See* Eisenberg, *supra* note 3, at 1830 ("[Directness] has no rational connection with the intent-to-benefit test or, for that matter, with anything else."). Nonetheless, some courts have purported to determine third-party enforcement rights in part on that basis, and this Court has occasionally endorsed a similar test. *See German Alliance Ins. Co. v. Home Water Supply Co.*, 226 U.S. 220, 230 (1912) ("Before a stranger can avail himself of the exceptional privilege of suing for a breach of an agreement to which he is not a party, he must, at least show that it was intended for his direct benefit."); *see also Robins Dry Dock & Repair Co. v. Flint*, 275 U.S. 303, 307 (1927) (quoting *German Alliance*).

To the extent directness matters, the Covered Entities directly benefit from the contract and are to receive performance directly.[13]

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12. *See* Eisenberg, *supra* note 3, at 1380 n. 85 (collecting cases).

13. This conclusion is clear from the contract's terms, and other direct interactions between Petitioners and the Covered Entities are established in guidance found in the May 7, 1993, *Federal Register*, to which the contract's preamble refers. *See* 58 Fed. Reg. 27289 (requiring that drug manufacturers "remit a rebate directly to the covered entity (or provide for a credit)" and, inversely, that covered entities shall be directly liable to manufacturers under a penalty provision related to resale restrictions). *Cf.* 42 U.S.C. § 256b(a)(5)(D) (referring to "the agreement between the entity and the manufacturer under this paragraph").

Similarly, the *Second Restatement*, perhaps confusingly, suggests that reasonable reliance of third-party beneficiaries can bear on their ability to enforce a contract:

> Either a promise to pay the promisee's debt to a beneficiary or a gift promise involves a manifestation of intention by the promisee and promisor sufficient, in a contractual setting, to make reliance by the beneficiary both reasonable and probable. Other cases may be quite similar in this respect. . . . Where there is doubt whether such reliance would be reasonable, considerations of procedural convenience and other factors not strictly dependent on the manifested intention of the parties may affect the question whether under Subsection (1) recognition of a right in the beneficiary is appropriate. In some cases an overriding policy, which may be embodied in a statute, requires recognition of such a right without regard to the intention of the parties.

*Second Restatement* § 302 cmt. d.

To the extent reliance matters, the Covered Entities, given even the text of the Agreement alone, reasonably could have relied on receiving the price promised for their benefit.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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# APPENDIX

## APPENDIX OF *AMICI CURIAE*[1]

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# AMICUS CURIAE BRIEF

No. 09-1273

IN THE

# Supreme Court of the United States

ASTRA USA, INC., ET AL.,
*Petitioners,*

v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,
*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## BRIEF OF FEDERAL COURTS PROFESSORS AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT


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*Textile Workers Union of Am. v. Lincoln Mills of Ala.*,
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Statute of Westminster II, 13 Edw. I, c. 50
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OTHER MATERIALS

Anthony J. Bellia, Jr., *Article III and the Cause of Action*, 89 IOWA L. REV. 777 (2004) ..... 6, 21, 22, 24

3 W. Blackstone, COMMENTARIES (1769) ..... 19

2 E. Coke, INSTITUTES ON THE LAWS OF ENGLAND (6th ed. 1681) ..... 19

1 COMYNS' DIGEST (1822) ..... 18

E. ALLAN FARNSWORTH, CONTRACT (4th ed. Aspen Publ. 2004) ..... 23

Thomas W. Merrill, *The Disposing of the Legislature*, 110 COLUM. L. REV. 452 (2010) ..... 15

Lumen N. Mulligan, *Federal Courts Not Federal Tribunals*, 104 NW. U. L. REV. 175 (2010) ..... 7, 27, 28

Lumen N. Mulligan, *A Unified Theory of 28 U.S.C. § 1331 Jurisdiction*, 61 VAND. L. REV. 1667 (2008) ..... 27

JOSEPH M. PERILLO, CALAMARI AND PERILLO ON CONTRACTS (6th ed. Thomson Reuters 2009) ..... 23

Theodore F. T. Plucknett, *Case and the Statute of Westminster II*, 31 COLUM. L. REV. 778 (1931) ..... 18

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19 CHARLES A. WRIGHT, ARTHUR R. MILLER & EDWARD E. COOPER, FEDERAL PRACTICE & PROCEDURE § 4515 (2007) ..... 8, 12

Donald H. Zeigler, *Rights, Rights of Action, and Remedies: An Integrated Approach*, 76 WASH. L. REV. 67 (2001) ..... 18

## INTEREST OF *AMICI CURIAE*[1]

*Amici curiae* are scholars with expertise in federal jurisdiction, federal courts and constitutional law who have an interest in the proper interpretation of questions of federal common law and inferred-cause-of-action doctrine. In *Amici*'s view, the decision by the Ninth Circuit Court of Appeals in this case correctly holds federal common law applicable to this question of contract interpretation and should be affirmed. Additionally, *Amici* consider Petitioners' inferred-cause-of-action arguments inconsistent with the original meaning of Article III and an overextension of this Court's precedent.

## INTRODUCTION

This is a contract case arising under federal common law. Respondent Santa Clara County ("Santa Clara") seeks to hold Petitioners, pharmaceutical manufacturers, accountable for breaching their contractual promises to sell drugs at reduced prices. Below, the Ninth Circuit held that Santa Clara was an intended third-party beneficiary and thus able to sue Petitioners in an ordinary contract action under federal common law. *Amici* urge this Court to affirm.

In 42 U.S.C. § 256b(a)(1), Congress directs the Secretary of the Department of Health and Human Services ("HHS") to enter into contracts with phar-

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represents that no counsel for a party authored this brief in whole or in part and that none of the parties or their counsel, nor any other person or entity other than *amici*, and their counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for *amici* also represent that all parties have consented to the filing of this brief, and letters reflecting their blanket consent to the filing of *amicus* briefs have been filed with the Clerk.

maceutical manufacturers to ensure that "covered entities"—state and local public hospitals, community health centers, and other providers of safety-net health services—receive pharmaceutical products at significantly reduced prices.[2] In reference to § 340B of the original Public Health Service Act of 1944, this drug discounting program is commonly referenced as the "§ 340B program" and § 256b(a)(1) "covered entities" are often referred to as "§ 340B entities." HHS and Petitioners entered into the § 340B program contract that is at issue here: the Pharmaceutical Pricing Agreement ("PPA"). Pet. App. 165a–181a. The PPA sets forth a formula, which incorporates statutory language from § 256b, for determining discounted pricing for pharmaceutical products that are to be sold to § 340B entities. *Id.* at 170a–171a (PPA ¶ II(a)-(g)). Santa Clara purchases pharmaceuticals on behalf of county-run, federally qualified health centers, which are § 340B covered entities within the meaning of the PPA. *Id.* at 167a (PPA ¶ I(e)); *see also* 42 U.S.C. § 256b(a)(4) (defining covered entities).

Santa Clara alleges that Petitioners failed to properly reduce pharmaceuticals purchased by it and other similarly situated § 340B entities as required by the PPA, causing millions of dollars in damages. J.A. 50–54 (Second Am. Cmpt. ¶¶ 56–64). Santa Clara seeks to recover these damages from the alleged breach of the PPA by way of a federal common

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[2] The statute requires that the Secretary "enter into an agreement with each manufacturer of covered drugs under which the amount required to be paid . . . to the manufacturer for covered drugs . . . purchased by a covered entity . . . does not exceed an amount equal to the average manufacturer price for the drug under [§ 1396r-8(k)(1)] in the preceding calendar quarter, reduced by [a] rebate percentage described in [§ 256b(a)(2)]." 42 U.S.C. § 256b(a)(1).

law, third-party-beneficiary breach of contract cause of action. *Id.* at 63–64 (Second Am. Compl. ¶¶ 101–04); Pet. App. 180a (PPA ¶ VII(g)) (choice of law clause selecting federal common law).

The District Court dismissed the third-party-beneficiary claim on Petitioners' FED. R. CIV. P. 12(b)(6) motion. Pet. App. 119a. The Ninth Circuit reversed, see *id.* at 30a-58a, holding that § 340B entities, like Santa Clara, "are intended direct beneficiaries of the PPA and have the right as third parties to bring claims for breach of that contract." *Id.* at 36a. *Amici* urge this Court to affirm.

## SUMMARY OF ARGUMENT

I. This Court should affirm the court of appeals' opinion and conclude that Santa Clara's third-party-beneficiary claim to enforce the PPA is governed by federal common law. Federal common law enforcement of the PPA follows from the fact that HHS is a party to the contract and the PPA's choice of law clause selects federal common law. *See Clearfield Trust Co. v. United States*, 318 U.S. 363, 366 (1943); Pet. App. 180a (PPA ¶ VII(g)). Furthermore, Congress' use of the term "agreement" in § 256b(a)(1) evidences its intent that this Court deploy traditional common law of contract to enforce the PPA. *See Field v. Mans*, 516 U.S. 59, 70 (1995) (holding that when Congress deploys terms having well-defined meanings at common law, this Court must give the term that meaning); RESTATEMENT (SECOND) OF CONTRACTS § 1 & cmt. a (1979) (defining contract and agreement as a legally enforceable promise). As a result, this Court should deploy common law of contract principles to determine Santa Clara's status as an intended beneficiary under the PPA. *See Int'l Assoc. of Machinists, AFL-CIO v. Central Airlines, Inc.*,

372 U.S. 682, 691–93 (1963) (holding a collective-bargaining contract entered into pursuant to statutory command enforceable as a matter of federal common law). Petitioners' assertions to the contrary, see Pet. Br. 21–25, the fact that § 256b(a)(1) directs the Secretary to enter into contracts with Petitioners does not strip the enforcement of the PPA of its common law status. *See Jackson Transit Auth. v. Local Div. 1285*, 457 U.S. 15, 21 (1982) (reversing "the Court of Appeals[, which] treated this [enforcement of a statutorily directed agreement] as a private right of action case, [because] it does not fit comfortably in that mold.") (citation omitted); *United States v. Seckinger*, 397 U.S. 203, 209–10 & n.13 (1970) (holding that statutory authority for the government to enter into contracts leads to federal common law enforcement of such contracts); *Central Airlines, Inc.*, 372 U.S. at 693 (holding a contract entered into pursuant to statutory command enforceable as a matter of federal common law); *Textile Workers Union of Am. v. Lincoln Mills of Ala.*, 353 U.S. 448, 456–57 (1957) (finding statutory command to create a body of federal contract law to govern labor-management disputes does not disturb that law's federal common law status). Nor does the fact that the PPA incorporates provisions of § 256b into the contract itself transform this Court's normal federal common law enforcement regime into an inferred-cause-of-action regime. *See Mobil Oil Exploration and Producing Southeast, Inc. v. United States*, 530 U.S. 604, 614 (2000) (enforcing government contracts under general principles of contract law—not inferred-cause-of-action doctrine—even though the contracts incorporated substantial portions of the Outer Continental Shelf Lands Act into the agreements); *Central Airlines*, 372 U.S. at 694 (enforcing collective-bargaining

agreement as a matter of federal common law of contract even though many of the alternative-dispute-resolution provisions were statutorily required).

II.A. Arguing that Santa Clara's federal common law claim is the functional equivalent of a claim inferred from statute, Petitioners and their supporting *amici* (with the notable exception of the United States) assert that *Alexander v. Sandoval*, 532 U.S. 275, 286–87 (2001), marks a sea-change in statutory inferred-cause-of-action jurisprudence, contending the opinion holds that the federal courts lack power to infer causes of action from statute, including § 256b. *See* Pet. Br. 18–20; PhRMA Br. 5–7; Chamber of Commerce Br. 8–9. Petitioners err on this point. The question before the *Sandoval* Court was whether to infer a cause of action from *agency regulation*. *See Sandoval*, 532 U.S. at 278 (stating the question presented as one of regulatory inference—not statutory). The *Sandoval* holding does not address inferring causes of action from *statute*. *See Jackson v. Birmingham Bd. of Educ.*, 544 U.S. 167, 178 (2005) ("*Sandoval* held that private parties may not invoke Title VI *regulations* to obtain redress for disparate-impact discrimination.") (emphasis added). Moreover, this Court has twice inferred a cause action from federal statutes since the *Sandoval* opinion, further demonstrating Petitioners' position as unsound. *See CBOCS W., Inc. v. Humphries*, 553 U.S. 442, 452–53 (2008) (inferring a retaliatory discrimination cause of action from 42 U.S.C. § 1981); *Jackson*, 544 U.S. at 177–78 (extending the inferred private right of action for Title IX suits to include retaliation claims).

II.B. Moreover, the overwhelming Founding-era authority demonstrates that the power to infer causes of action from statutes adheres to the original un-

derstanding of Article III judicial power. *See, e.g.*, *Ashby v. White*, (1703) 92 Eng. Rep. 126, 136–39 (K.B.) (inferring a cause of action for the failure, contrary to statute, to tally votes in a parliamentary election); Anthony J. Bellia, Jr., *Article III and the Cause of Action*, 89 IOWA L. REV. 777, 838–51 (2004) (providing an original-meaning discussion of Article III and the power of federal courts to infer causes of action). At the time of the Founding, "[i]f a statute did not expressly confer a remedy on the plaintiff, a cause of action [at law] for its violation would lie . . . if one of the forms of action—e.g., debt, case, assumpsit—provided a remedy for the kind of injury that the statutory violation caused." Bellia, 89 IOWA L. REV. at 840–41. The common law, moreover, has recognized third-party-beneficiary claims since at least 1677. *See Dutton v. Poole*, (1677) 83 Eng. Rep. 523 (K.B.), *aff'd* (1679) 83 Eng. Rep. 156 (Ex. Ch.). As a result, should this Court decide that finding a federal common law, third-party-beneficiary claim to enforce the PPA is the functional equivalent of inferring a cause of action under the statute, there are no original-meaning-based interpretations of Article III supporting Petitioners' broad-based prohibition upon inferring a cause of action from § 256b. *See* Bellia, 89 IOWA. L. REV. at 851.

III. Santa Clara's assertion of a federal common law claim to enforce the PPA does not create separation-of-powers concerns, contrary to the suggestion of Petitioners and supporting *amicus* United States Chamber of Commerce. *See* Pet. Br. 17–19; Chamber of Commerce Br. 5. Traditional statutory construction tools illuminate strong congressional intent to enforce the PPA by way of the federal common law of contract, see *infra* pp. 7–14, which distinguishes

*Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.* from the case at bar. *See* 552 U.S. 148, 164–65 (2008) (finding no congressional intent for private aiding-and-abetting causes of action). Moreover, the separation-of-powers position presented in *Stoneridge* rides on the faulty notion that only a federal cause of action vests jurisdiction under 28 U.S.C. § 1331. *See* Lumen N. Mulligan, *Federal Courts Not Federal Tribunals*, 104 NW. U. L. REV. 175, 182–208 (2010) (tracing the history of this line of argumentation and concluding that it is founded upon a defective understanding of 28 U.S.C. § 1331 doctrine). This Court's renewed commitment to federal jurisdiction without the need for a congressional cause of action, see *Grable & Sons Metal Prods., Inc. v. Darue Eng'g & Mfg.*, 545 U.S. 308, 314 (2005) (holding that federal question jurisdiction may vest under § 1331 without a federal cause of action), undercuts the notion that inferring a cause of action from § 256b violates separation-of-powers principles. *See Cannon v. Univ. of Chi.*, 441 U.S. 677, 746 n.17 (1979) (Powell, J., dissenting) (recognizing this issue).

## ARGUMENT

### I. SANTA CLARA'S THIRD-PARTY-BENEFICIARY CLAIM IS CONTROLLED BY FEDERAL COMMON LAW.

This is a federal common law of contract case. The happenstance that Santa Clara assumes, for the purposes of this suit, that § 256b does not imply an action for a third-party-beneficiary claim directly under the statute, see Pet. App. 22a n.15, does not preclude it from relying upon congressional intent to create a federal common law remedy. Nor does § 256b's undergirding of the PPA affect the federal common law status of its enforcement. First, stan-

dard federal common law doctrine establishes its applicability to the enforcement of the PPA. Second, Congress is empowered to select by statute federal common law enforcement of certain fields, which it chose to do here. Third, the fact that § 256b(a)(1) directs the Secretary to enter into contracts with Petitioners does not transform this rather straightforward federal common law question into an issue of whether a third-party-beneficiary claim may be inferred from § 256b directly. Fourth, the PPA's incorporation of statutory language lacks this transformative effect as well.

First, blackletter federal common law doctrine supports its application to the interpretation of the PPA. HHS is a party to the PPA, rendering the contract subject to federal common law enforcement. *See Clearfield Trust*, 318 U.S. at 366 (holding the United States commercial transactions subject to federal common law); 19 CHARLES A. WRIGHT, ARTHUR R. MILLER & EDWARD E. COOPER, FEDERAL PRACTICE & PROCEDURE § 4515 & n.10 (2007) (collecting cases establishing the proposition that federal common law governs "the validity, interpretation, or enforcement of government contracts"). Moreover, the PPA's choice of law provision selects federal common law. Pet. App. 180a (PPA ¶ VII(g)). This Court, then, as a matter of federal common law may readily look to general principles of contract law for the relevant third-party-beneficiary rule to apply to Santa Clara's claim under the PPA. *See Priebe & Sons, Inc. v. United States*, 332 U.S. 407, 411 (1947) ("It is customary, when Congress has not adopted a different standard, to apply to the construction of government contracts the principles of general contract law."). Pursuant to these general principles of

contract law, intended third-party beneficiaries may enforce government contracts such as the PPA. *See Arthur Andersen LLP v. Carlisle*, 556 U.S. ___, ___, 129 S. Ct. 1896, 1902 (2009) ("'traditional principles' of state law allow a contract to be enforced by or against nonparties to the contract through . . . 'third-party beneficiary theories'") (quoting 21 R. Lord, WILLISTON ON CONTRACTS § 57:19, p. 183 (4th ed. 2001)); RESTATEMENT (SECOND) OF CONTRACTS § 313(1) ("The rules stated in this Chapter[, relating to third-party beneficiaries,] apply to contracts with a government or governmental agency except to the extent that application would contravene the policy of the law authorizing the contract or prescribing remedies for its breach.").[3]

Second, Congress may direct by statute that certain fields be governed by federal common law without robbing those fields of their common law character. This Court has often so held. *See Rush Prudential HMO, Inc. v. Moran*, 536 U.S. 355, 377 (2002) ("Congress intended a 'federal common law of rights and obligations' to develop under ERISA."); *Texas Indus., Inc. v. Radcliff Materials, Inc.*, 451 U.S. 630, 640, 642 (1981) (instructing that federal common law may be crafted pursuant to statutory directive). In particular, Congress may choose to regulate certain fields by statutorily directing parties to enter into contracts and enforcing these agreements as a matter of common law. *See Jackson Transit*, 457 U.S. at 21 (holding statutorily directed agreements are to be enforced pursuant to state contract law and specifi-

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[3] Whether Santa Clara is an intended, third-party beneficiary of the PPA as a matter of contract law is beyond the scope of this brief. *Amici* contend only that this question should be determined as a matter of federal common law of contract.

cally reversing "the Court of Appeals[, which] treated this as a private right of action case, [because] it does not fit comfortably in that mold.") (citation omitted); *Central Airlines*, 372 U.S. at 693 (holding a contract entered into pursuant to statutory command is, "like the Labor Management Relations Act s 301 contract, . . . a federal contract and is therefore governed and enforceable by federal [common] law, in the federal courts.").

Congress took precisely this route here by choosing to enforce reduced pharmaceutical pricing to § 340B entities by contract. Congress directed the Secretary to "enter into an agreement with each manufacturer of covered drugs." 42 U.S.C. § 256b(a)(1). When Congress deploys a term such as "agreement," absent strong evidence to the contrary, this Court must give that term its established common law meaning. *See Field*, 516 U.S. at 70 ("It is well established that where Congress uses terms that have accumulated settled meaning under the common law, a court must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of these terms.") (internal quotations and citations omitted). The term "agreement" is a well understood synonym for contract. *See* RESTATEMENT (SECOND) OF CONTRACTS § 1, cmt. a ("The word 'contract' is . . . . a synonym for 'agreement.'"). Furthermore, the American usage of the terms "contract" and "agreement" are universally understood to mean "a promise or a set of promises for the breach of which the law gives a remedy." *Id.* at § 1; *see also Bowsher v. Merck & Co., Inc.*, 460 U.S. 824, 864 (1983) (Blackmun, J., concurring in part and dissenting in part) ("It is a fundamental canon of statutory construction that 'unless otherwise defined, words

will be interpreted as taking their ordinary, contemporary, common meaning.' In its ordinary meaning, a 'contract' is a legally enforceable bargain.") (citations omitted). Thus Congress, by directing HHS to enter into an "agreement," directed the federal courts to remedy breaches of the PPA by way of common law contract jurisprudence. *See Jackson Transit*, 457 U.S. at 20–21 ("[S]ince § 13(c) contemplates . . . collective-bargaining agreements between those parties . . . it is reasonable to conclude that Congress expected the . . . collective-bargaining agreement, like ordinary contracts, to be enforceable by private suit upon a breach.") (internal citation omitted); *id.* at 30 (Powell, J., concurring) (noting that when "Congress . . . provide[s] for the making of contracts . . . it must have intended [for them] to be enforced."); *Central Airlines*, 372 U.S. at 693 (similar).

Third, the fact that § 256b(a)(1) directs the Secretary to enter into contracts with Petitioners does not strip the enforcement of these contracts of their federal common law status. In fact, this Court has held that statutory authorization to enter into a contract is a paramount reason to interpret government contracts pursuant to federal common law. *See Seckinger*, 397 U.S. at 209–10 & n.13 ("[W]e agree with the court of appeals that federal law controls the interpretation of the contract. This conclusion results from the fact that the contract was entered into pursuant to authority conferred by federal statute.") (citations omitted). Indeed, it is now well established that when Congress regulates a field by the use of the traditional tools of contract law, this Court holds such contracts enforceable pursuant to the federal common law of contracts rather than by way of inferred-cause-of-action doctrine. *See, e.g., Jackson*

*Transit*, 457 U.S. at 21 (rejecting enforcement by way of an inferred cause of action in favor of contract law enforcement);[4] *Central Airlines, Inc.*, 372 U.S. at 691 ("If these contracts are to serve this function under s 204, their validity, interpretation, and enforceability cannot be left to the laws of the many States, for it would be fatal to the goals of the Act if a contractual provision contrary to the federal command were nevertheless enforced under state law or if a contract were struck down even though in furtherance of the federal scheme."); *Lincoln Mills*, 353 U.S. at 456–57 (finding statutory directive to create a body of federal contract law to govern labor-management disputes without disturbing that law's federal common law status); *see also Granite Rock Co. v. International Broth. of Teamsters*, 561 U.S. ___, ___, 130 S. Ct. 2847, 2855 n.2 (2010) (reaffirming the holding in *Lincoln Mills* as one of federal common law). As a result, the statutory directive in § 256b(a)(1) to the

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[4] Legislative history may lead to the conclusion, in certain cases, that state common law of contracts, as opposed to federal, should control statutorily commanded agreements. *See Jackson Transit*, 457 U.S. at 29 ("Given this explicit legislative history, we cannot read § 13(c) to create federal causes of action for breaches of § 13(c) agreements . . . . The legislative history indicates that Congress intended those contracts to be governed by state law.") (footnote omitted). Of import here, even though the *Jackson Transit* Court found federal common law of contract inapposite, it, nonetheless, held that the 49 U.S.C. § 1609(c) agreements at issue were enforceable as a matter of common law of contract—not inferred-cause-of-action doctrine. *Id.* at 21. Further, unlike the PPA agreement at issue here, the contract at issue in *Jackson Transit* lacked the federal government as a contractual party. *Id.* at 18 (finding the agreement at issue was between a union and a local transit authority). When the federal government contracts, however, its agreements are governed under federal common law. *See* 19 WRIGHT ET AL., at § 4515 & n.10.

Secretary to enter into agreements with Petitioners strengthens the position that the PPA should be enforced pursuant to federal common law.

Fourth, Petitioners' cries that the PPA's incorporation of provisions of § 256b into the contract turns this federal common law suit into an inferred-cause-of-action claim are to no avail. This Court held to the contrary in *Mobil Oil*, 530 U.S. 604 (2000). In *Mobil Oil*, the government entered into, and breached, contracts with petrochemical producers that incorporated several provisions of the Outer Continental Shelf Lands Act and attendant regulations as contractual promises. *Id.* at 614. Nevertheless, this Court enforced the provisions as a matter of contract law—not inferred-cause-of-action doctrine. *Id.* at 607 ("When the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals.") (internal quotations omitted); *id.* at 614 (citing the RESTATEMENT (SECOND) OF CONTRACTS and leading contract treatises for the proposition that "relevant contract law entitles a contracting party to restitution if the other party 'substantially' breached a contract or communicated its intent to do so."); *see also Central Airlines*, 372 U.S. at 694 (enforcing collective-bargaining agreement as a matter of federal common law of contract even though many of the alternative-dispute-resolution provisions were statutorily required). The Court should adopt this same contract-law approach to the enforcement of the PPA and its incorporation of provisions of § 256b. Indeed, this contract-law approach seems especially apt here given that Congress mandated that HHS regulate pharmaceutical prices by way of contract.

*See* 42 U.S.C. § 256b(a)(1); *Seekinger*, 397 U.S. at 209–10 n.13; *Central Airlines*, 372 U.S. at 691–93.

## II. EVEN IF SANTA CLARA'S FEDERAL COMMON LAW, THIRD-PARTY-BENEFICARY CLAIM IS VIEWED AS THE FUNCTIONAL EQUIVALENT OF INFERRING A CLAIM FROM § 256b, THIS COURT RETAINS THE ARTICLE III POWER TO INFER A CAUSE OF ACTION.

### A. Petitioners' reliance upon *Alexander v. Sandoval* is misplaced because *Sandoval* addressed this Court's power to infer causes of action from *agency regulation*—not *statute*.

Arguing that Santa Clara's federal common law claim is the functional equivalent of a claim inferred from § 256b(a)(1) directly, Petitioners and their supporting *amici* (with the notable exception of the United States) suggest that *Sandoval*, 532 U.S. at 286–87, marks a *fait accompli* regarding the power of the federal courts to infer causes of action from federal statutes; *viz.*, they contend that *Sandoval* bars the practice. *See* Pet. Br. 18–20; PhRMA Br. 5–7; Chamber of Commerce Br. 8–9. Petitioners' reliance upon *Sandoval*, however, does not support their position that this Court lacks power to infer a third-party-beneficiary cause of action from § 256b, even if this Court views the finding of such a federal common law action to enforce the PPA as the functional equivalent of inferring a third-party action directly from the statute.[5]

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[5] As argued above, see *supra* pp. 7–14, *Amici* do not support the notion that this Court should deploy the same analysis to the task of finding a federal common law, third-party-

This Court's own precedent post-*Sandoval* belies Petitioners' view. Indeed, this Court has inferred a cause action from federal statute twice since the *Sandoval* opinion. *See Humphries*, 553 U.S. at 452–53 (inferring a retaliatory discrimination cause of action from 42 U.S.C. § 1981); *Jackson*, 544 U.S. at 177–78 (extending the inferred private right of action for Title IX suits to include retaliation claims and specifically rejecting the argument that *Sandoval* marked the end of the power of the federal courts to infer causes of action in appropriate cases); *see also* Thomas W. Merrill, *The Disposing of the Legislature*, 110 COLUM. L. REV. 452, 465–66 (2010) (reviewing the Court's contemporary inferred-cause-of-action doctrine and concluding that "no majority opinion has yet to enforce . . . [the] position that any cause of action must be found in the express language of the statute, not derived by inference from legislative history."). Indeed, it is informative in this regard to recognize that the United States, as *amicus* supporting Petitioners, refuses to endorse Petitioners' overly broad reading of *Sandoval*. *See* United States Br.

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beneficiary cause of action to enforce the PPA as it would use if it were determining whether to infer an action directly from § 256b. But even if this Court adopts Petitioners' equivalency position on the question of whether a third-party-beneficiary claim lies, *Amici* do not concede that the substantive elements of a federal common law, third-party-beneficiary claim would be the functional equivalent of an action inferred directly from § 256b. For instance, an action inferred directly from § 256b would likely attach duties to all producers of pharmaceuticals that meet statutory requirements, whereas a federal common law of contract claim could only be brought against signatories to the PPA. *See* RESTATEMENT (SECOND) CONTRACTS § 304 (limiting the scope of third-party-beneficiary claims to "promisors").

21–22 (mentioning *Sandoval* only twice in its brief and not for this expansive interpretation).

Indeed, *Humphries* and *Jackson* demonstrate that Petitioners erroneously elevate *dicta* that addressed statutory inferences in the *Sandoval* opinion above the actual holding of the case. The issue in *Sandoval* was whether a private, disparate-impact cause of action could be inferred from an *agency regulation*—not whether a cause of action could be inferred from a federal statute. *See Sandoval*, 532 U.S. at 278 ("This case presents the question whether private individuals may sue to enforce disparate-impact *regulations* promulgated under Title VI.") (emphasis added). The *Sandoval* Court held that a private right of action could not be inferred from the *agency regulation* at issue in that case. *See id.* at 291 ("[W]hen a statute has provided a general authorization for private enforcement of regulations, it may perhaps be correct that the intent displayed in each regulation can determine whether or not it is privately enforceable. But it is most certainly incorrect to say that language in a regulation can conjure up a private cause of action that has not been authorized by Congress.").

This case is not one in which Santa Clara seeks to infer a cause of action from an agency regulation. Even if this Court treats the determination of whether the federal common law of contract embraces the third-party enforcement of the PPA as the functional equivalent of inferring a third-party cause of action claim directly under § 256b, the Court's holding in *Sandoval* is not on point because such an inference would be one from statute—not regulation. *See Jackson*, 544 U.S. at 178 (rejecting the notion that *Sandoval* prohibits the inference of a cause of action

from a *statute* because "*Sandoval* held that private parties may not invoke Title VI *regulations* to obtain redress for disparate-impact discrimination.") (emphasis added).

### B. The original meaning of Article III empowers this Court to infer a third-party-beneficiary cause of action from § 256b.

Even if this Court views the recognition of a federal common law, third-party-beneficiary claim to enforce the PPA as the functional equivalent of inferring a cause of action directly from § 256b, the original meaning of Article III judicial power confirms that this Court is authorized to infer a cause of action from § 256b. *See* U.S. CONST., Art. III § 1 (vesting the federal courts with "judicial power"). As a result, this Court should read the holding of *Sandoval* as limited to the question presented in that case—whether a court may infer causes of action from agency regulation. *See Sandoval*, 532 U.S. at 278. Adopting such a reading—as this Court did in *Jackson*, 544 U.S. at 178—best comports with the original meaning of Article III.

#### 1. *English common law at the time of the Founding fully recognized the power of the courts to infer causes of action from statutes.*

The power of federal courts to infer causes of actions from statutes is inherent to the Anglo-American conception of judicial power as deployed by the Framers of Article III of the Constitution. Legal scholars agree that the power of the Anglo-American courts to infer causes of action was recognized more than seven centuries ago in the Statute of Westminster II. *See* 13 Edw. I, c. 50 (1285) (Eng.) ("Moreover,

concerning the Statutes provided where the Law faileth, and for Remedies, lest Suitors coming to the King's Court should depart from thence without Remedy, they shall have Writs provided in their Cases . . . .").[6] King's Bench, as early as 1703, held that courts of law are empowered to infer causes of action from statutes. *See Ashby*, 92 Eng. Rep. at 136–39 (inferring a cause of action for the failure to tally votes in a parliamentary election as directed by statute); *see also Couch v. Steel*, (1854) 118 Eng. Rep. 1193, 1196–98 (K.B.) (inferring a cause of action from a statute requiring merchant vessels to carry appropriate medicines while at sea); *Anonymous*, (1703) 87 Eng. Rep. 791, 791 (Q.B.) ("[W]here-ever a statute enacts anything, or prohibits anything, for the advantage of any person, that person shall have remedy to recover the advantage given him, or to have satisfaction for the injury done him contrary to law by the same statute; for it would be a fine thing to make a law by which one has a right, but no remedy but in equity."). Moreover, this practice of inferring causes of action at law is fully recognized in the leading Founding-era common law commentaries. *See, e.g.*, 1 COMYNS' DIGEST 442 (1822) ("So, in every case, where

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[6] There is a wealth of scholarly commentary on this front. *See, e.g.*, Donald H. Zeigler, *'Rights, Rights of Action, and Remedies': An Integrated Approach*, 76 WASH. L. REV. 67, 71 n.12 (2001) (tracing the power of the federal courts to infer causes of action from statutes to the Statute of Westminster II); Susan J. Stabile, *The Role of Congressional Intent in Determining the Existence of Implied Private Rights of Action*, 71 NOTRE DAME L. REV. 861, 864 (1996) (arguing that common law courts had full authority to infer actions from statutes); Theodore F. T. Plucknett, *Case and the Statute of Westminster II*, 31 COLUM. L. REV. 778, 797–98 (1931) (discussing the attribution of the practice of inferring actions from statutes to the Statute of Westminster II).

a statute enacts, or prohibits a thing for the benefit of a person, he shall have a remedy upon the same statute for the thing enacted for his advantage, or for the recompence of a wrong done to him contrary to the said law."); 3 W. Blackstone, COMMENTARIES *23, *51, *109, *123 (1769) (similar); 2 E. Coke, INSTITUTES ON THE LAWS OF ENGLAND 55 (6th ed. 1681) (similar).

2. *Early American common law opinions confirm the power of the courts to infer causes of action from statutes.*

This common law practice of inferring causes of action from statutes, moreover, was not limited to English practice. Antebellum decisions from state high courts, often citing English cases such as *Ashby*, further demonstrate that the power to infer a cause of action from a statute was part of the original understanding of Article III judicial power. *See, e.g.*, *Stearns v. Atl. & St. Lawrence R.R. Co.*, 46 Me. 95, 115 (1858) (citing *Ashby* for the proposition that the courts can provide remedies for injuries to statutory rights); *Stout v. Keyes*, 2 Doug. 184, 187 (Mich. 1845) ("It is a general principle of the common law, that whenever the law gives a right, or prohibits an injury, it also gives a remedy by action; and, where no specific remedy is given for an injury complained of, a remedy may be had by special action on the case."); *Calking v. Baldwin*, 4 Wend. 668, 671 (N.Y. Sup. Ct. 1830) (presenting as the general rule that "if a statute gives a remedy in the affirmative, without a negative expressed or implied, for a matter which was actionable at common law, the party is not deprived of his common law remedy, but may elect to take it or that offered by the statute").

Furthermore, this Court has often relied upon inferred-cause-of-action jurisprudence's ancient lineage as precedent to infer a cause of action from federal statute. *See Texas & Pacific Railway Co. v. Rigsby*, 241 U.S. 33, 39–40 (1916) (citing COMYNS' DIGEST, Blackstone, *Couch* and *Anonymous* as authority to infer a cause of action under Section 2 of the Safety Appliance Act of 1910); *see also Franklin v. Gwinnett County Pub. Sch.*, 503 U.S. 60, 66 (1992) ("From the earliest years of the Republic, the Court has recognized the power of the Judiciary to award appropriate remedies to redress injuries actionable in federal court."); *Merrill Lynch, Pierce, Fenner & Smith, Inc. v. Curran*, 456 U.S. 353, 374 & n.52 (1982) (citing to *Rigsby* and Founding-era English authority that support the practice of inferring causes of action); *California v. Sierra Club*, 451 U.S. 287, 299–300 (1981) (Stevens, J., concurring) (noting that "implication of private causes of action was a well-known practice at common law and in American courts" and citing early English authorities); *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 26 & n.2 (1979) (White, J., dissenting) (citing to *Rigsby* and Founding-era English authority that support the practice of inferring causes of action); *Cannon*, 441 U.S. at 689 & n.10 (same); *Montana-Dakota Utilities Co. v. Northwestern Public Service Co.*, 341 U.S. 246, 261 (1951) (Frankfurter, J., dissenting) ("Courts . . . are organs with historic antecedents which bring with them well-defined powers. They do not require explicit statutory authorization for familiar remedies to enforce statutory obligations. A duty declared by Congress does not evaporate for want of a formulated sanction.") (citations omitted). At other times, this Court has attributed the power of the federal courts to infer causes of action from federal statutes as part

of the holding of *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803). *See, e.g., Jett v. Dallas Indep. Sch. Dist.*, 491 U.S. 701, 742 (1989) (Brennan, J., dissenting) (listing five pre-*Rigsby* inferred cause of action cases, including *Marbury*); *Tex. & New Orleans R.R. Co. v. Bhd. of Ry. & S.S. Clerks*, 281 U.S. 548, 569–70 (1930) (citing *Marbury* as authority to infer a cause of action from federal statute).

3. *This Court retains power to infer a third-party-beneficiary cause of action from § 256b, assuming Founding-era common law recognized third-party-beneficiary claims.*

Against this backdrop of the centuries-old tradition of Anglo-American courts' ability to infer causes of action from statute, it is clear that the original meaning of Article III judicial power encompasses the ability of federal courts to infer causes of action from federal statutes. *See* Bellia, 89 IOWA L. REV. at 838–51. *Ashby*, and the other leading Founding-era cases, lead to the conclusion that at that time, "[i]f a statute did not expressly confer a remedy on the plaintiff, a cause of action [at law] for its violation would lie . . . if one of the forms of action—e.g., debt, case, assumpsit—provided a remedy for the kind of injury that the statutory violation caused." *Id.* at 840–41; *accord Bullard v. Bell*, 4 F. Cas. 624, 639 (C.C.D.N.H. 1817) (No. 2,121) (Story, Circuit Justice) (holding that "[a]n action adapted to the nature of the case" must be "moulded according to the forms and distinctions of the common law").

While an original-meaning interpretation of Article III does not support an unfettered power to infer causes of action, the original understanding of Article III judicial power finds that when (1) the plaintiff has been injured in a manner that would have been re-

cognizable as an injury at Founding-era common law, and (2) the injury would have given rise to a Founding-era common law form of action to remedy it, a federal court is empowered to infer a cause of action from a federal statute. *Id.* at 851. Petitioners, and *amici* in support of Petitioners, therefore, improperly rely upon *dicta* in *Sandoval* for the proposition that the federal courts lack the power to infer a cause of action from § 256b. *See* Bellia, 89 IOWA. L. REV. at 851 (illustrating that this reading of *Sandoval* "does not squarely reflect the historical practice of English and state courts. . . . [T]hey did afford remedies . . . for some statutory violations, even remedies that legislatures had not expressly authorized, . . . . when that violation resulted in the kind of injury or wrong . . . that a form of action was available to remedy."). Rather, the best original-meaning interpretation of Article III shows that if Santa Clara could have brought a third-party-beneficiary claim at common law under a then-existing writ, this Court retains the power under Article III to infer such a cause of action under § 256b.

4. *Because Founding-era common law provided third-party beneficiaries relief by way of writ of assumpsit, this Court retains Article III authority to infer third-party-beneficiary claims under § 256b.*

A third-party-beneficiary claim, such as is at issue here, was remediable at common law by way of a writ of assumpsit. The right of third-party beneficiaries to enforce contracts by way of writ of assumpsit was well established at the time the Constitution was ratified. As early as 1677, King's Bench had adopted the doctrine of third-party-beneficiary enforcement of contract. *Dutton*, 83 Eng. Rep. 523

(holding a contract between a father and son, which intended to benefit the father's daughter, was enforceable by her via writ of assumpsit).[7] By the time of the Revolutionary War, third-party-beneficiary doctrine was so entrenched as a matter of English common law that Lord Mansfield thought the issue beyond questioning. *See Martyn v. Hind*, (1776) 98 Eng. Rep. 1174, 1178 (K.B.) (Lord Mansfield) (approving third-party-beneficiary enforcement under writ of assumpsit and stating "[a]s to the case of *Dutton versus Poole*, . . . it is matter of surprise, how a doubt could have arisen in that case.").

Antebellum American cases adopted third-party-beneficiary doctrine as well. As early as 1806, American courts, citing *Dutton*, held contracts enforceable by intended, third-party beneficiaries. *See Hind v. Watts*, 2 Watts 104 (Pa. 1833) (recognizing third-party-beneficiary claim); *Crocker v. Higgins*, 7 Conn. 342, 347 (1829) (citing *Dutton* and *Martyn* and holding in an equitable action seeking specific performance that "it is now established, that a third person may maintain a suit on a parol promise, made for his benefit, although he is not a party to the contract."); *Arnold v. Lyman*, 17 Mass. 400, 405 (1821) (affirming a verdict in assumpsit and holding "[g]enerally he for whose interest a promise is made, may maintain an action upon it, although the promise be made to another, and not to him."); *Cumberland v. Codrington*, 3 Johns. Ch. (NY) 299, 255 (1817) (Kent, Ch.) (citing *Dutton* for the proposition that "[i]t has been

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[7] Contract-law scholars regard *Dutton* as the seminal third-party-beneficiary case. *See, e.g.*, JOSEPH M. PERILLO, CALAMARI AND PERILLO ON CONTRACTS 577–78 (6th ed. Thomson Reuters 2009); E. ALLAN FARNSWORTH, CONTRACT 653–56 (4th ed. Aspen Publ. 2004).

held, that if one person makes a promise to another, for the benefit of a third person, that third person may maintain an action at law on that promise."); *Schermerhorne v. Vanderheyden*, 1 Johns. Rep. 140 (N.Y. Sup. 1806) (per curiam) ("[W]e are of opinion, that where one person makes a promise to another for the benefit of a third person, that third person may maintain an action on such promise. This was the doctrine of the King's Bench, in the case of *Dutton and wife v. Pool*, (2 Lev. 210.) affirmed in error. The same principle has, since that time, been repeatedly sanctioned by the decisions of the English courts.").

Given these authorities—when coupled with the congressional intent that § 340B agreements, such as the PPA, should be enforced pursuant to federal common law of contract, see *supra* pp. 7–14—there is no original-meaning Article III barrier to this Court recognizing Santa Clara's federal common law, third-party-beneficiary cause of action to enforce the PPA. Founding-era common law readily enforced third-party-beneficiary suits and, as a matter of original meaning of Article III judicial power, this Court is authorized to infer actions from statutes if plaintiff's statutory rights could have been enforced by way of such a common law writ. *See* Bellia, 88 IOWA L. REV. at 840–41. Therefore, even if this Court concludes that finding a federal common law, third-party-beneficiary cause of action to enforce the PPA is the functional equivalent of inferring a third-party cause of action directly under § 256b, this Court should find no Article III hurdle to affirming the court of appeals' ruling on such grounds. *See id.* at 851 (Founding-era courts "did afford remedies . . . for some statutory violations, even remedies that legislatures had not ex-

pressly authorized, . . . . when that violation resulted in the kind of injury or wrong . . . that a form of action was available to remedy."); *see also Transamerica*, 444 U.S. at 19 (holding as a matter of inferred-cause-of-action jurisprudence that "when Congress declared in § 215 that certain contracts are void, it intended that the customary [common law of contracts based] legal incidents of voidness would follow, including the availability of a suit for rescission, . . . injunction . . ., and for restitution.").

## III. SANTA CLARA'S TRADITIONAL BREACH OF CONTRACT CAUSE OF ACTION TO ENFORCE THE PPA DOES NOT VIOLATE SEPARATION-OF-POWERS PRINCIPLES.

The separation-of-powers concerns expressed by Petitioners and the Chamber of Commerce are without merit. *See* Pet. Br. at 17–19; Chamber of Commerce Br. 5. Petitioners and the Chamber of Commerce rely heavily upon selectively pruned language from *Stoneridge* in making their argument; namely: "the Judiciary's recognition of an implied private right of action necessarily extends its authority to embrace a dispute Congress has not assigned it to resolve. . . ., conflict[ing] with the authority of Congress under Art. III to set the limits of federal jurisdiction.'" 552 U.S. at 164–65 (quoting *Cannon*, 441 U.S. at 746 (Powell, J., dissenting)). Nevertheless, this case is distinguishable from *Stoneridge* on congressional intent grounds and Justice Powell's *Cannon* dissent does not provide a sound basis for a separation-of-powers argument here.

Santa Clara's third-party-beneficiary claim is substantially distinguishable from *Stoneridge*. In *Stoneridge*, congressional intent to infer a cause of action from § 10b was lacking altogether. *Id.* at 158,

162–63, 166. Indeed, the Court in *Stoneridge* limited its discussion of separation of powers and inferred-cause-of-action doctrine to those situations where there was no congressional intent to create a private cause of action. 552 U.S. at 164. Here, by contrast, Congress's intent to enforce § 256b(a)(1) by way of a federal common law of contract cause of action is manifest. *See supra* pp. 7–14. The holding in *Stoneridge*, which declined to infer a cause of action in the face of no congressional intent, therefore, is not on point. *See Stoneridge*, 552 U.S. at 158, 162–63, & 166.

Petitioners, it seems, seek to have their cake and eat it too. On the one hand, they argue that recognizing Santa Clara's federal common law, third-party-beneficiary action to enforce the PPA is the functional equivalent of inferring a cause of action directly under § 256b. *See* Pet. Br. 21–25. Yet, on the other hand, they refuse to acknowledge the overwhelming indicia of congressional intent to enforce § 256b agreements by way of the federal common law of contract. *See* Pet. Br. at 42–45. Petitioners cannot have it both ways. If, as Petitioners and *amici* in support urge, finding a federal common law right to enforce the PPA is the functional equivalent of inferring a cause of action from § 256b directly, then the evidence of congressional intent to enforce § 256b agreements by way of the federal common law of contract, see *supra* pp. 7–14, should be viewed as the functional equivalent of congressional intent to infer a cause of action directly under § 256b. Even if this Court views the recognition of the federal common law, third-party-beneficiary enforcement of the PPA by Santa Clara through an inferred-cause-of-action lens, it should properly weigh Congress' intent to

create a federal common law of contract enforcement scheme in § 256b(a)(1). Such a weighing of congressional intent here is at odds with the lack of congressional intent found in *Stoneridge*. *See* 552 U.S. at 164.

Finally, the *Stoneridge* quotation selected by Petitioners and the Chamber of Commerce, 552 U.S. at 164–65, relies primarily upon Justice Powell's dissent in *Cannon*. *See Cannon*, 441 U.S. at 746 (Powell, J., dissenting). In *Cannon*, Justice Powell argued that only a federal cause of action may vest jurisdiction under 28 U.S.C. § 1331, rendering judicial inferences of a cause of action a jurisdiction-expanding act—contrary to separation-of-powers norms placing the control over lower federal court jurisdiction in Congress' hands. *See id.* at 745–46; *see also* Mulligan, 104 NW. U. L. REV. at 190 (elaborating on Justice Powell's position). Justice Powell's position is unpersuasive, however, because it rides upon an unreflective invocation of the so-called Holmes test, see *Am. Well Works Co. v. Layne & Bowler Co.*, 241 U.S. 257, 260 (1916) (Holmes, J.), that is not compatible with this Court's broader § 1331 doctrine.

Justice Powell's absolutist presentation of the Holmes test (*i.e.*, a federal cause of action is the sole necessary and sufficient condition for taking § 1331 jurisdiction) is not compatible with this Court's post-*Cannon* § 1331 jurisprudence. *See, e.g.*, Lumen N. Mulligan, *A Unified Theory of 28 U.S.C. § 1331 Jurisdiction*, 61 VAND. L. REV. 1667, 1725 (2008) (concluding that the existence of a federal cause of action is neither a necessary nor sufficient condition for the vesting of § 1331 jurisdiction). The Court brought this incompatibility to the fore recently when it renewed its commitment to the rule that § 1331 juris-

diction may lie without a congressionally created, federal, cause of action. *See Grable & Sons*, 545 U.S. at 314 (holding that federal question jurisdiction may lie under § 1331 without a federal cause of action); *Franchise Tax Bd. of Cal. v. Constr. Laborers Vacation Trust for S. Cal.*, 463 U.S. 1, 27–28 (1983) ("Congress has given the lower federal courts jurisdiction to hear . . . cases in which a well-pleaded complaint establishes . . . that the plaintiff's right to relief necessarily depends on resolution of a substantial question of federal law."); *Gully v. First Nat'l Bank in Meridian*, 299 U.S. 109, 112 (1936) (noting that a federal question exists when a "right or immunity created by the Constitution or laws of the United States [is] an element, and an essential one, of the plaintiff's cause of action"); *Smith v. Kansas City Title & Trust Co.*, 255 U.S. 180, 201–02 (1921) (same). This re-embrace of federal question jurisdiction without the need for a congressionally created cause of action undercuts Justice Powell's notion that inferring a cause of action from statute, including § 256b, violates separation of powers, because it rejects the major premise of the argument. *See* Mulligan, 104 NW. U. L. REV. at 203–05 (arguing that *Grable & Sons* undermines Justice Powell's position).

Justice Powell recognized as much in his *Cannon* dissent. *See Cannon*, 441 U.S. at 746 n.17 (Powell, J., dissenting). Citing *Smith*, Justice Powell found it "instructive to compare decisions implying private causes of action to those cases that have found non-federal causes of action cognizable by a federal court under § 1331." *Id.* He found that "the net effect [of bringing a non-federal cause of action under *Smith*] is the same as implication of a private action directly from the constitutional or statutory source of the fed-

eral law elements." *Id.* As a result, Justice Powell concluded that hearing suits such as *Smith* and *Grable & Sons* are, in his view, extra-jurisdictional in just the same manner as the inference of a federal cause of action. *Id.* Given the incompatibility of Justice Powell's separation-of-powers argument with *Smith*-style § 1331 jurisdiction, this Court precluded the adoption of Justice Powell's position by reaffirming that the federal courts may take § 1331 jurisdiction in certain cases without a congressionally created cause of action in *Grable & Sons*. 545 U.S. at 314. The combination, therefore, of congressional intent for federal common law enforcement of § 256b(a)(1) contracts, see *supra* pp. 7–14, coupled with the parsimonious construction of § 1331 doctrine in Justice Powell's *Cannon* dissent, lead *Amici* to the conclusion that there are no significant separation-of-powers concerns in this case.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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# AMICUS CURIAE BRIEF

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# In the Supreme Court of the United States

ASTRA USA, INC., ET AL.,

*Petitioners,*

v.

COUNTY OF SANTA CLARA, ON BEHALF OF ITSELF AND ALL OTHERS SIMILARLY SITUATED,

*Respondent.*

*On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit*

## BRIEF FOR KANSAS, ARIZONA, MISSOURI, WEST VIRGINIA AND THE DISTRICT OF COLUMBIA AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

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## QUESTION PRESENTED

Whether, when Congress implements aspects of the Medicaid and Section 340B programs by directing the Secretary of Health and Human Services to enter into contracts with drug manufacturers, the breach of such a contract is actionable by the intended third-party beneficiaries of the contract—such as the States, local governments, or health care providers—on whose behalf Congress specifically directed the Secretary to enter the contract?

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*Harris v. McRae*,
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*Int'l Assoc. of Machinists, AFL-CIO v. Central Airlines, Inc.*,
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*Jackson Transit Auth. v. Local Div. 1285*,
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*Massachusetts, et al. v. Mylan Laboratories, et al.*,
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*Nevada ex rel. Steinke v. Merck & Co.*,
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*Pharm. Research & Mfrs. of America v. Walsh*,
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*United States v. Seckinger*,
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**OTHER MATERIALS**

21 R. Lord, Williston on Contracts § 57:19, (4th ed. 2001) . . . . . 23

DOJ Press Release, Assistant Attorney General Tony West Speaks at Press Conference Announcing Major Settlements with Pharmaceutical Manufacturers (Dec. 7, 2010), http://www.justice.gov/civil/opa/pr/speeches/2010/civ-speech-101207.html . . . . . 17

H.R. Rep. No. 102-384(II) (1992) . . . . . 32

Letter from Public Hospital Pharmacy Coalition and National Association of Community Health Centers to Centers for Medicare and Medicaid Services at 2 (Feb. 17, 2006), http://www.nachc.org /client/documents/ issues-advocacy/policy-library/medicare-medicaid-policy-updates/340B-PDP_Contracting.pdf . . . . . 32

Letter from Sen. Charles Grassley to HHS at 1 (Sept.1, 2005) ("A drug pricing violation under

the Medicaid rebate program attributable to overstated 'best price' may also signal a violation under the 340B program."), *available at* www.drugdiscountmonitor.com/members/HRSA_Letter.pdf. . . . . 30

Merck Settles For $649 Million for Failure to Pay Medicaid Rebates (Feb. 8, 2008), http://www.namfcu.net/press/merck-settles-for-649-million-for-failure-to-pay-medicaid-rebates/ . . . . . 14

NAMFCU Press Release, AstraZeneca To Pay $520 Million to settle Claims of Off-Label Drug Marketing (April 27, 2010), http://www.namfcu.net/press/astrazeneca-to-pay-520-million-to-settle-claims-of-off-label-drug-marketing/ . . . 16

NAMFCU Press Release, Aventis Pharmaceutical, Inc. resolves allegations for misreporting Best Prices for Azmacort, Nasacort and Nasacort AQ (June 5, 2009), http://www.namfcu.net/press/aventis-pharmaceutical-inc/). . . . . 14

NAMFCU Press Release, Bristol-Myers Squibb Settles For $389 Million to Resolve Medicaid Pharmaceutical Pricing and Marketing Allegations (July 15, 2008), http://www.namfcu.net/press/bristol-myers-squibb-settles-for-389-million/. . . . . 14

NAMFCU Press Release, Four Pharmaceutical Companies Agree to Pay $124 Million for Alleged Submission of False Claims to Medicaid (Oct. 19, 2009), http://www.namfcu.net/press/four-pharmaceutical-companies-agree-to-pay-

124-million-for-alleged-submission-of-false-claims-to-medicaid/ . . . . . 16

NAMFCU Press Release, Pfizer Inc to Pay $2.3 Billion in Historic Settlement (Sept. 2, 2009), http://www.namfcu.net/ press/pfizer-inc-to-pay-2-3-billion-in-historic-settlement/ . . . . . 15

NAMFCU Press Release, Pharmaceutical Company Pays $42.5 Million To Resolve Fraud Allegations (Mar. 16, 2010), http://www.namfcu.net/press/pharmaceutical-company-pays-42-5-million-to-resolve-fraud-allegations/ . . . . . 16

OIG, *Medicaid Drug Rebates — Sales to Repackagers Excluded from Best Price Determinations*, A-06-00-00056, at 4 (Mar. 2001) http://oig.hhs.gov/oas/reports/region6/60000056.pdf. . . . . 31

Restatement (Second) of Contracts §304 (1981) . . 6

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www.namfcu.net/about-us/what-is-medicaid-fraud . 19

www.namfcu.net/resources/medicaid-fraud-reports-newsletters/2010-publications/10MarApr.pdf (at p. 1) . . . . . 13

www.nlj.com ("DOJ settles with three pharmaceutical companies for $421 million over inflated drug prices") (Dec. 7, 2010) . . . . . 4, 5

## INTEREST OF THE *AMICI* STATES

Medicaid is a perhaps unique example of cooperative federalism. Under this massive and important program, the federal government and the States are engaged in a joint enterprise in which both sovereigns participate significantly and directly. For Medicaid to function, both sovereigns make significant financial commitments, and both partners play important administrative and oversight roles.

1. Because of the States' significant partnership with the United States in funding, implementing, and administering the Medicaid and related programs, the States have a direct and substantial interest in the question presented in this case. Like the Respondent in this case, the States can and have brought breach of contract claims against drug manufacturers on the legal ground that the States are intended third-party beneficiaries of at least some agreements between the Secretary of Health and Human Services (hereinafter "the Secretary" or "HHS") and drug manufacturers.

For instance, the States have brought suit seeking to enforce the Medicaid Rebate Agreement against drug manufacturers that breached that contract by falsely reporting the manufacturers' average and best prices. Like the 340B program at issue in this case, payments under the Rebate Agreement depend on manufacturers' average and best prices, and the States' claims in such cases largely mirror the claim the Respondent makes in this case.

Indeed, approximately 35 states have joined the federal government in such a suit in federal court in Massachusetts. *See, e.g., United States, et al. v. Wyeth*,

No. 06-11724-DPW (D. Mass.). A primary legal theory of the States in *Wyeth* is that the States are intended third-party beneficiaries to the Rebate Agreement. The Rebate Agreement clearly states that the Secretary enters the contract "on behalf of [HHS] and all States and the District of Columbia (except to the extent that they have in force an Individual State Agreement)." Joint Appendix (hereinafter "J.A.") 69. The States certainly view themselves to be intended third-party beneficiaries of the Rebate Agreement—indeed to hold otherwise would make the provision for States to enter their own rebate agreements with manufacturers nonsensical—and the States would be very unpleasantly surprised by a contrary conclusion.

2. Furthermore, the States are the primary enforcers of many aspects of the Medicaid statutes and regulations. In 1977, Congress authorized the States to have a Medicaid Fraud Control Unit ("MFCU"), and many states have had MFCUs since 1978. *See* www.namfcu.net. Since Congress made MFCUs Mandatory in 1993, every state and the District of Columbia has such an investigative and prosecutorial enforcement unit, except North Dakota which received a waiver from HHS and does not have a MFCU. The 50 MFCUs generally are located within the offices of state attorneys general (in 43 states), although six states and the District of Columbia locate their MFCU elsewhere in state government.

The MFCUs have the authority to investigate and prosecute claims against those who overcharge Medicaid programs, as well as authority to pursue Medicaid provider fraud generally. MFCUs are intended to operate like a "strike force", with

investigators, auditors and attorneys working together to uncover, investigate and prosecute Medicaid fraud. Such investigations certainly can lead and have led to the discovery of pricing fraud by drug manufacturers providing drugs to Medicaid programs. Indeed, the State MFCUs have joined in prosecuting a number of such cases over the years, sometimes involving tens and even hundreds of millions of dollars. The States and their MFCUs stand ready and willing to investigate and prosecute such cases as appropriate.

There is a National Association of Medicaid Fraud Control Units, founded in 1978, to provide a forum for sharing of information concerning Medicaid fraud, to improve the quality of Medicaid fraud investigations and prosecutions, and to provide technical assistance to members. All 50 State MFCUs are members of this association, which is headquartered in Washington, D.C., at the offices of the National Association of Attorneys General. The association is staffed by an Executive Director and other administrative staff. *See* www.namfcu.net.

Ultimately, any objective look at the history and evolution of Medicaid makes clear several facts that demonstrate the prominent and important role that the States play in this area: (1) Medicaid involves substantial expenditures of both federal *and State* funds; (2) the federal government establishes many of the rules and regulations for Medicaid, but *the States* administer and implement Medicaid on the ground on a day-to-day basis; and (3) throughout Medicaid's history, *the States* have played a primary role in investigating, policing, and prosecuting Medicaid fraud, precisely because the federal government long

has recognized that it is not able to do so alone for a variety of reasons.

Thus, the States have very direct financial and pragmatic interests in important legal questions regarding the Medicaid program, including the third-party beneficiary question in this case.

## STATEMENT

1. To ensure that public hospitals, community health centers, and others serving indigent patients pay the lower prescription drug prices often available to Medicaid, Congress directed the Secretary to enter an "agreement" with drug manufacturers to limit "the amount required to be paid" for drugs purchased by "covered" entities. 42 U.S.C. §256b(a)(1) ("Public Health Services Act §340B"). Under the 340B program, the petitioners in this case all signed what are referred to as Pharmaceutical Pricing Agreements ("PPAs") with the Secretary. Each such contract includes a promise from the manufacturer to "charge [340B] entities a price" that, for non-generic drugs, is normally no higher than the manufacturer's Best Price ("BP") in the marketplace.

Unfortunately, significant evidence suggests that not all drug manufacturers have always accurately reported their prices for various Medicaid program purposes. Indeed, just recently, in what is known as an "average wholesale price" fraud case, the United States Department of Justice "reached settlements totaling $421 million with a trio of pharmaceutical companies that reported falsely inflated drug prices used to set government health care reimbursement rates." *See* www.nlj.com ("DOJ settles with three

pharmaceutical companies for $421 million over inflated drug prices") (Dec. 7, 2010). Indeed, these recent settlements were reported as "part of more than $5 billion that the Justice Department's Civil Division and U.S. Attorney's offices have recovered in health care fraud cases since January 2009." *Id.*

2. In this case, Respondent County of Santa Clara became aware that drug manufacturers such as the petitioners had misreported their drug prices in violation of the PPAs the manufacturers signed under the 340B program. As a result, Respondent brought this suit on behalf of its 340B hospital and clinics and a class of similarly situated entities. Respondent relied on several legal theories in its complaint and amended complaints, but the only claim before this Court is Respondent's claim that 340B covered entities are intended third-party beneficiaries of the PPAs, and as such have the right to sue under federal law for the petitioners' breaches of those contracts.

2.a. The district court found that 340B "covered entities" are intended third-party beneficiaries under the PPAs, because the whole purpose of the PPAs is to have the manufacturers provide price discounts to 340B entities, which "suggests that Congress intended to benefit them [the 340B entities] directly." Appendix to the Petition for a Writ of Certiorari (hereinafter "Pet. App.") 117a. The district court nonetheless dismissed Respondent's claim on the ground that neither the relevant statutes nor the PPAs expressly authorize intended third-party beneficiaries to bring breach of contract claims. *Id.*

2.b. Following an initial appeal in which the court of appeals reversed the district court's dismissal of

Respondent's third-party beneficiary claim, on remand the district court entered a protective order at the request of petitioners during a discovery dispute. Respondent then took an interlocutory appeal. In that appeal, the court of appeals withdrew the mandate for its previous decision and reissued its original decision with little modification.

In its reissued opinion, the court of appeals, "[a]pplying the federal common law of contracts," held that 340B entities "are intended direct beneficiaries of [the PPAs]." Pet. App. 31a. (Petitioners notably do not take issue with that holding in this Court.) The court of appeals, however, rejected the district court's holding that such 340B entities needed express authorization to bring suit for breach of contract. Instead, the court pointed out that "the right to sue inheres in one's status as an intended beneficiary." *Id.* 39a (citing Restatement (Second) of Contracts §304 (1981) ("Restatement") ("A promise in a contract creates a duty in the promisor to any intended beneficiary to perform the promise, and the intended beneficiary may enforce the duty.")).

The court of appeals also rejected petitioners' argument that Respondent could not sue to enforce the PPAs unless the courts found that Respondent had an implied statutory right of action to enforce §256b. Pet. App. 50a-55a. Respondent conceded below that it had no such implied statutory right of action, and the court of appeals accepted that concession for purposes of its opinion, *id.* at 50a & n. 15, as should this Court.

The court of appeals concluded that the absence of an implied statutory right of action was irrelevant to the question whether an intended third-party

beneficiary can bring suit to enforce the PPAs. Instead, the court of appeals pointed out that the relevant question is whether Congress has displaced the otherwise generally applicable "federal common law contract remedy that the covered entities could invoke as intended beneficiaries of the [PPAs]." *Id.* at 54a. Finding nothing in the Medicaid statutes to indicate congressional intent to preclude this traditional common law remedy, the court of appeals rejected petitioners' argument, and held that intended third-party beneficiary suits are "wholly compatible with the Section 340B program's objectives." *Id.* at 55a.

## SUMMARY OF ARGUMENT

**I.A.** Medicaid is a perhaps unique example of cooperative federalism, one in which the States in many respects play a primary or co-equal role, and not a subservient or secondary role. The States pay a significant portion of all Medicaid costs, and all States (but one that obtained a waiver from HHS) have established active and successful Medicaid Fraud Control Units (MFCUs), precisely for the purpose of investigating and prosecuting false claims made against Medicaid programs, as well as Medicaid provider fraud in general.

**I.B.** Unfortunately, it is documented beyond dispute that fraud against the Medicaid program is a serious and ongoing problem, one that has cost taxpayers billions of dollars. Certainly, that has been the case with regard to prescription drugs, the sales of which can be worth a fortune to their manufacturers. When the prices the Medicaid program ultimately pays for prescription drugs depend on accurate price

reporting by manufacturers, the manufacturers' opportunity to profit from reporting inflated prices—and thus their incentives to be less than candid—are great, often to the tune of tens or even hundreds of millions of dollars, even on a monthly basis or for a single prescription drug. For example, recent settlements between the State MFCUs, the federal government, and drug manufacturers over the kind of pricing allegations at issue in this case easily total more than $1 billion, as described in detail below.

**I.C.** Thus, for decades—just as Congress intended—the States have been active investigators and prosecutors of Medicaid fraud. Indeed, the States have played that role at the express command of Congress, as well as at the encouragement of, and in cooperation with, HHS and the Secretary. Since at least 1977, Congress has made it clear that the federal government alone could not shoulder the burden of being the sole investigator and prosecutor of Medicaid fraud.

**II.A.** Under the Court's longstanding and well-settled precedent, the intended third-party beneficiaries of federal contracts have the traditional common law right to sue for breach of contract. That right is well-grounded in federal common law specifically, as well as the common law of contracts generally, where it has been recognized as the standard for well over 300 years.

The States have relied precisely on their intended third-party beneficiary status—for example under the state Medicaid Rebate Agreements (*see* J.A. 69)—to sue for breach of contract. Indeed, the States have done so in the very context of prescription drug

manufacturers misreporting their drug prices by inflating those prices to the detriment of the States and their Medicaid programs. Such intended third-party beneficiary enforcement is fully consistent with the intent of Congress under the Medicaid and 340B programs. Congress and HHS have *always* relied and counted upon fraud investigation and prosecution support from the States and other intended third-party beneficiaries of Medicaid programs. Indeed, such joint and cooperative enforcement responsibilities are as much a hallmark of the Medicaid program as the federal/state sharing of the funding, implementation, and administration of Medicaid generally.

**II.B.** This case simply is not an implied statutory right of action case. As this Court has recognized, an implied statutory right of action claim and a breach of contract claim in a setting like this are analytically and logically distinct claims, with each based on a different legal foundation and history. Furthermore, in this Court the petitioners do not challenge the consistent lower court holdings in this case that Respondent and the class it represents are in fact intended third-party beneficiaries of the PPAs. Furthermore, Respondent conceded below and acknowledges in this Court that it is not making any claim of an implied statutory right of action, and the court of appeals correctly assumed for purposes of its decision that no such claim was raised.

Allowing intended third-party beneficiaries to bring breach of contract claims in no way opens the door to end runs around the stringent standards for recognizing implied statutory rights of action. Rather, it will be the unusual case—of which the States submit Medicaid and Section 340B are the prime and perhaps

only examples—in which there is both (1) a federal contract like the state Rebate Agreement or the PPAs *and* (2) a federal statutory scheme so overtly and intricately intertwined with such contracts. Perhaps there are other examples, but the vast, vast majority of federal statutory schemes do not require and rely upon federal contracts to implement the statutory directives.

**II.C.** Both the States and 340B entities share the same interest in enforcing manufacturers' obligations under their Medicaid and 340B contracts. Third-party beneficiary suits provide States with an effective means to remedy manufacturers' breaches of those obligations; States also benefit when 340B entities discover and prove violations of the PPAs, because the manufacturers' breaches also violate the state Rebate Agreement.

The petitioners concede that the States' and 340B entities' interests are wholly aligned when it comes to best-price manipulation by manufacturers, a practice that unfortunately is demonstrably widespread. Any hypothetical conflict between the interests of the States and 340B entities in enforcing manufacturers' contracts is purely speculative and, indeed, seems quite unlikely ever to develop given the kinds of price-manipulation cases that actually have been litigated. Importantly, the States benefit when 340B entities receive the full price discounts to which those providers are entitled, because the State dollars spent reimbursing the 340B entities for drugs provided to the States' indigent populations accomplish more good and serve more citizens in need.

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At bottom, the state Medicaid Rebate Agreement and the PPAs at issue in this case present an unusual situation that both (1) merits recognition of the traditional common law right of intended third-party beneficiaries to sue for breach of contract and (2) does not open the door to claims by innumerable third party beneficiaries who do not have an implied statutory right of action.

## ARGUMENT

### I. As Congress Has Always Intended, The States Play A Prominent Role In The Medicaid Program, Including Pursuit Of False Claims And Fraud Through Third-Party Beneficiary Breach of Contract Suits.

#### A. Medicaid Is A Unique Instance Of Cooperative Federalism.

Medicaid and the related 340B program are part of a unique "system of cooperative federalism," *Harris v. McRae*, 448 U.S. 297, 301 (1980), where "the two governments [federal and state] are pursuing common purposes." *Pharm. Research & Mfrs. of America v. Walsh*, 538 U.S. 644, 666 (2003). Indeed, in general, the Medicaid program—as reflected in the relevant statutes and agreements such as the state Rebate Agreement and the PPAs that the Secretary enters—involves a unique level of close cooperation between the federal government and the States, each of which foots a significant portion of the costs of the program, and each of which shoulders a substantial share of the implementation, administration, and enforcement duties.

The cooperative federal-state framework underscores the notion that the States are intended third party beneficiaries of contracts entered into on their behalf by the Secretary under the Medicaid program. Since Medicaid's inception, the States and the federal government both have been responsible for symbiotic and coequal roles in the Medicaid system. In fact, although both the States and the federal government fund Medicaid, the States have primary authority to design and administer their Medicaid programs, with HHS playing a secondary administrative role. 42 U.S.C. § 1396 *et seq.*; *Connecticut Dept. of Social Services v. Leavitt*, 428 F.3d 138, 141 (2d Cir. 2005).

A state's Medicaid program must first be approved by HHS after meeting certain federal requirements. 42 U.S.C. § 1396a(a)-(b). But, in the end, a state's participation in Medicaid is optional. *Harris*, 448 U.S. at 301. Only after a state has made the policy decision to create a state Medicaid program does the federal government have any responsibility to or authority over that state's Medicaid operations. And, of course, only after HHS's approval is a state eligible for partial federal reimbursement of its Medicaid expenses. 42 U.S.C. § 1396a.

Just as two companies might agree to pool resources for the benefit of each, here the decision of the federal government and the States to enter into the Medicaid program as a joint enterprise creates a common interest in the effective and efficient administration of the program. This shared authority and interest, with the States developing and implementing their own Medicaid plans subject to ultimate federal approval before funding flows to the

state, makes the States truly equal partners with the federal government in the Medicaid context. In such a joint enterprise, there is no question that actions taken by one partner must necessarily have intended benefits or effects on the other partner, especially when the issue is the price Medicaid programs are to pay drug manufacturers.

### B. Medicaid Fraud By Drug Manufacturers Is A Serious Problem.

Since at least 1977, when it enacted the Medicare-Medicaid Fraud and Abuse Amendments, Pub. L. No. 95-142, Congress has recognized that Medicaid fraud in general is an extremely serious problem, one that likely costs taxpayers billions of dollars annually. Medicaid fraud has taken many forms, from the mundane (*e.g.*, using snippets of papers clips for root canal posts instead of proper stainless steel posts, *see* www.namfcu.net/resources/medicaid-fraud-reports-newsletters/2010-publications/10MarApr.pdf at p. 1), to massive schemes worth billions of dollars.

Drug manufacturers have been a significant part of the problem. In recent years alone, the State MFCUs and the federal government have joined forces to collect well more than $1 billion in settlements from drug manufacturers for the very type of price reporting fraud at issue in this case. Manufacturers repeatedly and substantially have underpaid Medicaid rebates to States by failing to give Medicaid programs the benefit of their actual "best price" in the marketplace for brand-name drugs. Under the Rebate Agreement, just as under the Medicaid statute, "best price" means "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider,

health maintenance organization, nonprofit entity, or governmental entity within the United States in the marketplace," (with certain exceptions), and "shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates." 42 U.S.C. § 1396r-8(c)(1)(C)(i); *see* Rebate Agreement § I(d) (J.A. 70-71).

Because a single, low-priced sale can establish a manufacturer's best price nationwide and thus require millions of dollars in additional Medicaid rebates to States, manufacturers' incentives to misreport best prices are great. Thus, Merck paid $649 million in part to resolve best-price misreporting claims concerning Vioxx, Zocor, and Pepcid.[1] Aventis agreed to pay $95.5 million to resolve allegations that it "knowingly misreported best prices for the steroid-based anti-inflammatory nasal sprays Azmacort, Nasacort and Nasacort AQ."[2] And Bristol-Myers Squibb similarly agreed to pay $389 million to resolve allegations of "[r]eporting inflated prices for various prescription drugs" and "[p]aying illegal remuneration to physicians, health care providers, and pharmacies to induce them to purchase" their drugs.[3] *See also*

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[1] Merck Settles For $649 Million for Failure to Pay Medicaid Rebates (Feb. 8, 2008), http://www.namfcu.net/press/merck-settles-for-649-million-for-failure-to-pay-medicaid-rebates/.

[2] NAMFCU Press Release, Aventis Pharmaceutical, Inc. resolves allegations for misreporting Best Prices for Azmacort, Nasacort and Nasacort AQ (June 5, 2009), http://www.namfcu.net/press/aventis-pharmaceutical-inc/).

[3] NAMFCU Press Release, Bristol-Myers Squibb Settles For $389 Million to Resolve Medicaid Pharmaceutical Pricing and Marketing Allegations (July 15, 2008), http://www.namfcu.net/press/bristol-myers-squibb-settles-for-389-million/.

Respondent's Br. 8-11 (describing certain of these and other settlements and guilty pleas resulting from best-price manipulation schemes).

Each of these settlements, as well as those discussed below, resulted from a *qui tam* case filed by a whistleblower. Representatives from a number of State MFCUs / Attorneys General offices then participated in the ensuing investigations and settlement negotiations on behalf of the settling States.[4]

In addition to best-price manipulation schemes, manufacturers also have engaged in other profitable yet illegal practices such as off-label marketing, making false statements about a drug to induce physicians to prescribe it, improperly classifying their drugs to lower the Medicaid rebate due, and misreporting their average wholesale prices.

For example, in the largest settlement in history in a health-care fraud matter, Pfizer agreed to plead guilty and pay $2.3 *billion* to resolve criminal and civil allegations that it defrauded the States and the federal government by generating illegal revenues through "off-labeling marketing campaigns that improperly promoted numerous drugs that Pfizer manufactures," including "Bextra, Geodon, Lyrica, Zyvox, Aricept, Celebrex, Lipitor, Norvasc, Relpax, Viagra, Zithromax, Zoloft and Zyrtec."[5] AstraZeneca similarly agreed to pay $520 million "to settle allegations it engaged in an

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[4] *See, e.g., id.*

[5] NAMFCU Press Release, Pfizer Inc to Pay $2.3 Billion in Historic Settlement (Sept. 2, 2009), http://www.namfcu.net/press/pfizer-inc-to-pay-2-3-billion-in-historic-settlement/.

off-label marketing campaign that improperly promoted the antipsychotic drug, Seroquel," in part by making "illegal payments to physicians, paying their way to travel to resort locations to 'advise' AstraZeneca about marketing messages for unapproved uses."[6]

Four manufacturers agreed to pay $124 million based on allegations they had "sold innovator [*i.e.*, brand-name] drugs that were manufactured by other companies and had classified those drugs as non-innovator drugs for Medicaid rebate purposes," thus "underpa[ying] their rebate obligations to the Medicaid Program."[7] Alpharma agreed to pay $42.5 million "to settle allegations of causing false or fraudulent claims . . . to be submitted to the Medicaid program . . . ."[8]

And, just recently, three manufacturers agreed to pay $421 million to resolve claims that they illegally reported inflated "average wholesale prices" that "allowed drug companies to create an incentive for the purchase of their drugs, since buyers could pay the drug companies one price and obtain government

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[6] NAMFCU Press Release, AstraZeneca To Pay $520 Million to settle Claims of Off-Label Drug Marketing (April 27, 2010), http://www.namfcu.net/press/astrazeneca-to-pay-520-million-to-settle-claims-of-off-label-drug-marketing/.

[7] NAMFCU Press Release, Four Pharmaceutical Companies Agree to Pay $124 Million for Alleged Submission of False Claims to Medicaid (Oct. 19, 2009), http://www.namfcu.net/press/four-pharmaceutical-companies-agree-to-pay-124-million-for-alleged-submission-of-false-claims-to-medicaid/.

[8] NAMFCU Press Release, Pharmaceutical Company Pays $42.5 Million To Resolve Fraud Allegations (Mar. 16, 2010), http://www.namfcu.net/press/pharmaceutical-company-pays-42-5-million-to-resolve-fraud-allegations/

payment at an inflated price and pocket the difference—essentially a kickback scheme funded by taxpayer dollars."[9] As an Assistant United States Attorney colorfully explained, "this practice within the pharmaceutical industry was widespread---so much so that instead of Average Wholesale Price, 'AWP,' it was jokingly said, really stood for: 'Ain't What's Paid.'"[10]

The preceding examples are by no means exhaustive. As they and other settlements demonstrate, Medicaid fraud schemes are myriad and widespread. Such schemes also can be very difficult to detect, as illustrated by the fact that fraud cases often have been initiated by insiders (whistleblowers) who have come forward with information that State and federal authorities otherwise might never have discovered.

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[9] DOJ Press Release, Assistant Attorney General Tony West Speaks at Press Conference Announcing Major Settlements with Pharmaceutical Manufacturers (Dec. 7, 2010), http://www.justice.gov/civil/opa/pr/speeches/2010/civ-speech-101207.html

[10] *Id.* To be clear, the average *wholesale* price (unlike average *manufacturer* price) does not play a role in determining Medicaid rebates or 340B drug discounts. But, like the numerous other schemes detailed, it illustrates the multifarious means that manufacturers have devised to profit illegally from Medicaid and related programs.

### C. For Decades—Just As Congress Intended—The States Have Played A Leading Role In Investigating and Prosecuting False Claims And Medicaid Fraud, Including Suits As Third-Party Beneficiaries To Enforce Federal Contracts.

Shortly after Congress passed the Medicare-Medicaid Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, seventeen states created MFCUs as authorized by the 1977 legislation. In 1993, Congress mandated that all states establish MFCUs. 42 U.S.C. § 1396(a)(61). As of 1995, all states (but North Dakota, which obtained a waiver from HHS) and the District of Columbia had MFCUs in place.

With considerable federal funding, and annual reporting and certification requirements through HHS, the MFCUs work closely and collectively with the United States to combat and deter Medicaid fraud through wide-ranging investigations and prosecutions of both civil and criminal cases. A general description of the MFCUs and their history can be found at www.namfcu.net/about-us/about-mfcu, website of the National Association of Medicaid Fraud Units, established in 1978 and headquartered in the offices of the National Association of Attorneys General in Washington, D.C.

The State MFCUs have been active and successful over the past 30 years in rooting out and punishing all sorts of Medicaid fraud across the nation. "The MFCUs have prosecuted individual providers such as physicians, dentists, and mental health professionals. In addition, the Units have also prosecuted fraud in

numerous segments of the health care industry, such as hospitals, nursing homes, home health care agencies, medical transportation companies, pharmacies, durable medical equipment companies, *pharmaceutical manufacturers* and medical clinics." www.namfcu.net/about-us/what-is-medicaid-fraud (emphasis added).

In some cases, the States have pursued claims as intended third-party beneficiaries of the Rebate Agreement. For example, in *Massachusetts, et al. v. Mylan Laboratories, et al.*, 357 F. Supp. 2d 314 (D. Mass. 2005), the Commonwealth of Massachusetts sued drug manufacturers for (1) fraudulently inflating Wholesale Acquisition Cost prices (causing the State to overpay pharmacies and other providers of generic prescription drugs) and, most directly relevant to this case, (2) reporting false "best prices" to the Secretary to decrease the amounts owed to the States under the Rebate Agreement.

For the Rebate Agreement claims, Massachusetts alleged (1) that the States are intended third-party beneficiaries to the rebate agreement and thus have a traditional common law claim for breach of contract, and (2) that the States have an implied statutory right of action under the relevant federal statutes governing the rebate agreement. The district court dismissed the implied right of action claim, as follows: "Here, because the statute unambiguously gives the Secretary the power to terminate the Rebate Agreement, renew it and impose federal penalties for false or untimely filings, I conclude that the states do not have a remedy under the statute. *This is not the end of the analysis, however, because the statute also requires the Secretary to enter into the Rebate Agreement on behalf of the state*

*and is silent on the scope of the available contractual remedies.*" 357 F. Supp. 2d at 326 (emphasis added).

Indeed, the district court went on to consider and uphold the States' claim as intended third-party beneficiaries of the Rebate Agreement. Noting that the Rebate Agreement was "signed by the manufacturers and the Secretary," the court pointed out that in "applying federal common law" a court "may look to the Restatement of Contracts for guidance regarding when a third-party beneficiary may sue." 357 F. Supp. 2d at 326. Observing that the Restatement expressly endorses the rights of intended third-party beneficiaries to sue for breach of contract, and noting that the key question is the "intent of the parties" to the contract, *id.*, the court turned to the Rebate Agreement. The Court correctly and pointedly observed that "the Rebate Agreement begins with the statement: 'The Secretary, on behalf of the Department of Health and Human Services *and all States* and the District of Columbia . . . [shall enter the agreement]." *Id.* at 327 (emphasis original).

Like this case, the drug manufacturers argued that where there is no implied statutory right of action, there cannot be an intended third-party beneficiary claim, but the district court rejected that assertion, relying on the:

> well-established propositions that "[w]hen the United States enters into contract relations, its rights and duties therein are governed generally by the law applicable to contracts between private individuals," and that when Congress uses language with a settled meaning at common law, Congress "presumably knows and

> adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken and the meaning its use will convey to the judicial mind unless otherwise instructed. In such case, absence of contrary direction may be taken as satisfaction with widely accepted definitions, not as a departure from them."

357 F. Supp. 2d at 327-28 (citing and quoting *Mobil Oil Exploration, Producing S.E., Inc. v. United States*, 530 U.S. 604, 607 (2000), and *Beck v. Prupis*, 529 U.S. 494, 500-01 (2000)).

According to the district court, "[t]hese two lines of case law together establish the rule that a beneficiary to a federal contract has the right to enforce an agreement imposing duties on a person contracting with the government so long as this is consistent with the statutory scheme, and not an end-run on it." 357 F. Supp. 2d at 328. Applying that standard to the state Rebate Agreement, the district court easily concluded that the "Best Prices Statute and the Rebate Agreement demonstrate a clearly expressed intent on behalf of the signatories to benefit the states by providing them with rebates. Medicaid is a unique 'system of cooperative federalism,' where the 'two governments are pursuing common purposes.'" *Id.* (internal citations omitted). The court then acknowledged that the Rebate Agreements "do not expressly provide a contract remedy to a state," although they do provide an "alternative dispute resolution" mechanism if the States provide incorrect information to the manufacturers. *Id.*

Ultimately, recognizing that the third-party beneficiary question under the Rebate Agreement "is an issue of first impression" and that "the contract is ambiguous," the Court noted that "the Rebate Agreement instructs the Court to construe it in a manner which 'best effectuates' the statutory scheme." 357 F. Supp. 2d at 328. The court then held that "[p]ermitting the states to sue as third-party intended beneficiar[ies] would advance the congressional objectives of reducing Medicaid drug costs." *Id.* Importantly, the Court recognized that the "close cooperation" between the federal government and the States under Medicaid "differentiates those cases which decline to find third-party beneficiary status in private individuals" and, "[i]ndeed, in its amicus brief, HHS stated that it would invite the states to join as plaintiffs in any litigation involving breach of contract." *Id.*

Furthermore, the district court's thoughtful opinion in *Mylan Laboratories*—recognizing the validity of third-party beneficiary claims by the State—provides a roadmap for properly analyzing and resolving this case. Following that map, which is based entirely on decisions of this Court as well as particular attention to the language of the Rebate Agreement, leads inexorably to the conclusion that intended third-party beneficiaries should be permitted to bring breach of contract claims in the context of the Medicaid and closely-related 340B programs.

## II. This Contract Case Falls Well Within The Venerable Common Law Doctrine Allowing Intended Third-Party Beneficiaries To Sue For Breach Of Contract, And This Suit Furthers The Goals Of Congress For The Medicaid and 340B Programs.

### A. Under Well-Established Anglo-American Law And The Court's Own Cases, Intended Third-Party Beneficiaries May Sue To Enforce Contracts.

The common law has recognized third-party beneficiary claims since at least the 1600s. *See, e.g.*, *Dutton v. Poole*, (1677) 83 Eng. Rep. 523 (K.B.), *aff'd* (1679) 83 Eng. Rep. 156 (Ex. Ch.). American courts have recognized third-party beneficiary claims since at least the early 1800s. *See, e.g.*, *Schermerhorne v. Vanderheyden*, 1 Johns. Rep. 140 (N.Y. Sup. 1806) (per curiam) ("[W]here one person makes a promise to another for the benefit of a third person, that third person may maintain an action on such promise. This was the doctrine of the King's Bench [citing *Dutton* and] . . . . [t]he same principle has . . . been repeatedly sanctioned by the decisions of the English courts."); *Arthur Andersen LLP v. Carlisle*, 556 U.S. ___, 129 S. Ct. 1896, 1902 (2009) ("'traditional principles' of state law allow a contract to be enforced by or against nonparties to the contract through . . . 'third-party beneficiary theories'") (quoting 21 R. Lord, Williston on Contracts § 57:19, p. 183 (4th ed.2001)).

Importantly, this Court has long and in several different contexts recognized that intended third-party beneficiaries may have the right to sue for breach of contract. *See* Respondent's Br. 31-32 (citing and

discussing third-party beneficiary cases of this Court dating back to the 19th century). Pursuant to these traditional contract law principles, intended third-party beneficiaries should be permitted to enforce government contracts such as the PPAs at issue in this case and the state Rebate Agreements.

Indeed, HHS generally has welcomed the States to join as plaintiffs in litigation involving claims for breach of the Rebate Agreement. In *United States, et al. v. Wyeth*, No. 06-11724-DPW (D. Mass.), more than 30 States now have intervened as parties in a suit against Wyeth for reporting false and inflated prices for particular prescription drugs for purposes of the rebate program. Both the *Mylan Laboratories* case, discussed above at 19-21, and the *Wyeth* case demonstrate that the States can and will bring significant third-party beneficiary breach of contract claims against drug manufacturers. Consequently, absent clear indication that Congress intended to preclude such suits, the Court should be loathe to strip the States of this important enforcement authority which is well-grounded in traditional common law contract principles.

As noted above at 19-21, in the *Mylan Laboratories* case, the district court held that States may sue as intended third-party beneficiaries to enforce the provision in the Medicaid Rebate Agreement requiring manufacturers to provide rebates to States. *See* 357 F. Supp. 2d at 328-29. The court first determined that "a beneficiary to a federal contract has the right to enforce an agreement imposing duties on a person contracting with the government so long as this is consistent with the statutory scheme, and not an end-run on it," and concluded that "[p]ermitting the states

to sue as third-party intended beneficiary would advance congressional objectives of reducing Medicaid drug costs." *Id.* The court relied in part on the Secretary's assertion, in an amicus brief filed in another case in Massachusetts, that, "to the 'extent that a state sues a drug manufacturer that failed to calculate its best price obligations in accordance with the Rebate Agreement or CMS guidance — but does not seek to impose any additional or contrary obligations — the state is merely enforcing the existing rebate program responsibilities and does not inject any more variation than if the Department of Justice brought suit.'" *Id.* at 329 (quoting U.S. Amicus Br. at 17, *In re Pharm. Indus. Avg. Wholesale Price Litig.*, No. 01-cv-12257-PBS (D. Mass. filed Apr. 5, 2004)).

The same reasoning is equally applicable to suits by 340B entities, where the third-party beneficiary contract action is based on the same statutory and contractual best-price standard applicable to the Medicaid Rebate Agreement. In contrast—and of grave concern to the States—a ruling that 340B entities may not sue as intended third-party beneficiaries would doubtless be invoked by drug manufacturers to argue that the States cannot enforce the Rebate Agreement as intended third-party beneficiaries.

An intended third-party beneficiary breach of contract action is an efficient and effective means for the States to ensure that they receive the full Medicaid rebates to which they are entitled—just as 340B entities can use such an action to obtain the full price discounts to which they are entitled. The standards for breach of contract actions are settled and straightforward, making such actions a valuable tool

in the States' enforcement arsenal. Unlike state and federal false claims or other fraud statutes, breach of contract actions do not require the plaintiff to prove the defendant's scienter. *See, e.g., Nevada ex rel. Steinke v. Merck & Co.*, 432 F. Supp. 2d 1082, 1087 (D. Nev. 2006) (Nevada False Claims Act requires "the knowing presentation of what is known to be false," thus precluding liability "through mere negligence") (internal quotation marks omitted); 31 U.S.C. § 3729(a)(1), (2) (requiring proof that a defendant "knowingly" made a false claim). For a variety of reasons, breach of contract actions are an important enforcement tool for the States in their efforts to combat Medicaid fraud.

**B. This Is A Breach Of Contract Case.**

The fundamental error that petitioners and their amici in this case—though not the United States, which raises very different arguments—invite this Court to make is to view the enforcement of the PPAs (and by implication other agreements that exist in the Medicaid context, such as the very important state Rebate Agreement that the Secretary expressly enters "on behalf of the States"), as raising the question whether Respondent has an implied statutory right of action to sue. In this context, however, breach of contract claims and implied statutory right of action claims are analytically distinct.

The PPAs are contracts, and are enforceable according to traditional contract law principles. The law of implied statutory rights of action and cases such as *Alexander v. Sandoval*, 532 U.S. 275 (2001), are thus irrelevant to the proper analysis. Charging 340B entities prices in excess of the ceiling price, or rebating

to the States less money than the States are due as a result of inaccurate best-price reporting is, pure and simple, a breach of contract; it is not a claim that arises by implication or otherwise under the Medicaid statutes or Section 340B, a point which the court of appeals correctly assumed below.

This Court has made clear in numerous cases that federal contracts entered into pursuant to statutory direction—even federal contracts expressly incorporating statutory requirements—do not themselves become "statutory" in nature; instead, they remain *contracts*, to be interpreted as such and subject to breach of contract claims. *See, e.g., Jackson Transit Auth. v. Local Div. 1285*, 457 U.S. 15, 21 (1982) (treating the enforcement of a statutorily directed agreement as a matter of contract law, not an implied statutory right of action); *United States v. Seckinger*, 397 U.S. 203, 209–10 & n.13 (1970) (contracts entered pursuant to statutory authority are enforced as contracts); *Int'l Assoc. of Machinists, AFL-CIO v. Central Airlines, Inc.*, 372 U.S. 682, 691–93 (1963) (holding that a collective-bargaining contract entered into pursuant to statutory command is enforceable as a contract); *see also* RESTATEMENT (SECOND) OF CONTRACTS § 313(1) ("The [third-party beneficiary] rules stated in this Chapter apply to contracts with a government or governmental agency except to the extent that application would contravene the policy of the law authorizing the contract or prescribing remedies for its breach.").

The fact that § 256b(a)(1) directs the Secretary to enter into contracts with drug manufacturers does not strip the PPAs of their status as contracts under traditional federal common law. *See, e.g., Central*

*Airlines, Inc.*, 372 U.S. at 693 (a contract entered pursuant to statutory directive is enforceable as a contract). Nor does the inclusion of statutory provisions in a federal contract transform a breach of contract claim into a matter of statutory enforcement. *See, e.g., Mobil Oil Exploration and Producing Southeast, Inc. v. United States*, 530 U.S. 604, 614 (2000) (government contracts are enforced according to contract law principles, and not as an implied statutory right of action, even when the contracts incorporate portions of federal statutes).

That is not to say that congressional authorization or directives to enter federal contracts is irrelevant. The statutory directive matters as an indication that the federal interest in such contracts is strong and, as a result, courts should interpret such contracts as a matter of federal common law, and not, for example, by resort to the law of any particular state. *See, e.g., Seckinger*, 397 U.S. at 209–10 & n.13 (contract must be interpreted as a matter of federal common law because "the contract was entered into pursuant to authority conferred by federal statute.") (citations omitted). Statutory authorization, however, does not turn all such federal contracts into additional statutory provisions, and does not require that such contracts be subjected to implied statutory right of action analysis. That is the error of petitioner and most of its amici (the United States notably does not endorse that error).

This case involves a breach of contract claim, and only such a claim. Thus, it is proper for federal courts to look to general principles of contract law to determine, as a matter of traditional common law, the appropriate rule for third-party beneficiary claims

under the PPAs. *See Priebe & Sons, Inc. v. United States*, 332 U.S. 407, 411 (1947) ("It is customary, when Congress has not adopted a different standard, to apply to the construction of government contracts the principles of general contract law.").

The Court should rely only on contract law principles to resolve the question whether Respondent may pursue this case, and not be led astray by petitioner's arguments about other irrelevant doctrines. Once the focus is properly restored to the contract law basis for Respondent's claim, the issues are plain: (1) For breach of the PPAs, may an intended third-party beneficiary bring suit? and (2) If so, is Respondent such an intended third-party beneficiary? The answer to both questions is a resounding yes, and Respondent's suit should proceed.

### C. The States And The 340B Entities Share The Same Interests In Remedying Breaches of the Medicaid Rebate Agreement and the PPAs.

States, like 340B entities, have a strong interest in the recognition of a third-party breach of contract action. Whether brought by States or 340B entities, breach of contract actions seek to apply the same best-price standard under which manufacturers are required to calculate both their Medicaid rebates to States and discounted prices to 340B entities. Importantly, where suits by 340B entities reveal that manufacturers have overcharged for covered drugs by inflating their best prices, States will benefit from being able to use those revelations to seek the best-price Medicaid rebates to which the States were

entitled, but which they did not receive.[11] Intended third-party beneficiary claims by the States and 340B entities thus are complementary of each other and further Congress's intent.

1. Relying on an argument that the United States made to the court below but which, with good reason, the United States does not repeat in this Court, petitioners claim that, in cases where a state rebate is not based on a manufacturer's best price, a reduction in average manufacturer price (AMP) may cause state Medicaid rebates to decline at the same time that 340B price discounts would increase. *See* Pet. Br. 40-41.[12] Petitioners suggest that this gives States an incentive in litigation to argue for higher AMPs, and for 340B entities to argue for lower AMPs, thus putting manufacturers at risk of "conflicting obligations." *Id.* at 40.

Petitioners' claim is speculative and meritless. Neither the petitioners here, nor the United States below, identified any instance of AMP manipulation by drug manufacturers to deprive States of Medicaid rebates.[13] Nor can they point to even a single example

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[11] *Cf.* Letter from Sen. Charles Grassley to HHS at 1 (Sept. 1, 2005) ("A drug pricing violation under the Medicaid rebate program attributable to overstated 'best price' may also signal a violation under the 340B program."), *available at* www.drugdiscountmonitor.com/members/HRSA_Letter.pdf.

[12] See 42 U.S.C. §1396r-8(c)(1)(A)(ii), (c)(1)(B) (providing that the minimum rebate for a brand-name drug is AMP less 15.1 percent). For other drugs (*e.g.*, generics), the minimum rebate is AMP less 11 percent. *See* 42 U.S.C. § 1396r-8(c)(3)(B).

[13] As shown above, manufacturers have manipulated their average *wholesale* price, but that average plays no role in the

among the numerous false claims act suits against and settlements with drug manufacturers in which AMP manipulation was the basis of the fraudulent scheme.

To the contrary, many of those suits involved best-price manipulation, *see supra* pp.14-15; Respondent's Br. 8-11, a situation in which petitioners *concede* that the States' and the 340B entities' interests are wholly aligned. *See* Pet. Br. 41. Indeed, it is readily apparent from the history of such suits that best-price manipulation is both easier to accomplish and far more lucrative than AMP manipulation. Because a single low-price sale can establish the best price nationwide, that factor can have a dramatic impact on both state Medicaid rebates and 340B drug price discounts.[14] Even if manufacturers were to engage in AMP manipulation, any hypothetical divergent interests between the States and the 340B entities would be no reason to deny either—or both—a breach of contract action in the far more lucrative and thus far more likely context of best-price manipulation.

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calculation of the discounts due to 340B entities and so provides no support for petitioners' claim that States and 340B entities have conflicting interests. *See supra* note 10.

[14] For example, in 2001, the HHS Inspector General found that five manufacturers improperly excluded from their best-price calculations low-price sales on 11 drugs to three health maintenance organizations that repackaged and resold the drugs under a private label; as a result, those manufacturers underpaid the $165 million in rebates owed to the States for a one-year period by nearly half, causing "the Medicaid drug rebate program [to] los[e] $80.7 million." OIG, *Medicaid Drug Rebates — Sales to Repackagers Excluded from Best Price Determinations*, A-06-00-00056, at 4 (Mar. 2001)http://oig.hhs.gov/oas/reports/region6/60000056.pdf.

2. Finally, both the States and the 340B entities benefit when the latter receive the full price discounts to which they are entitled. States rely on 340B entities to provide services to indigent state citizens. "Although 340B hospitals constitute less than 5 percent of all hospitals in the United States, they provide over 25 percent of the uncompensated health care for Americans."[15] As the House report accompanying the bill that became section 340B explained, the purpose of the statute was "to enable" 340B entities "to obtain lower prices on the drugs that they provide to their patients," thus "reaching more eligible patients and providing more comprehensive services." H.R. Rep. No. 102-384(II), at 7, 12 (1992).

States plainly benefit when 340B entities receive the full price discounts to which they are entitled. The more medical care 340B hospitals can provide with their limited resources and state reimbursement, the further state Medicaid budgets will go in serving the States' neediest citizens. Ultimately, allowing the States and the 340B entities alike to rely on traditional common law remedies available to intended third-party beneficiaries furthers the goals of Congress. Such actions will inure to the benefit of state Medicaid programs, 340B entities, and, most importantly, the poor and indigent persons that these cooperative programs exist to serve.

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[15] Letter from Public Hospital Pharmacy Coalition and National Association of Community Health Centers to Centers for Medicare and Medicaid Services at 2 (Feb. 17, 2006), http://www.nachc.org/client/documents/issues-advocacy/policy-library/medicare-medicaid-policy-updates/340B-PDP_Contracting.pdf

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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# AMICUS CURIAE BRIEF

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No. 09-1273

In the
# Supreme Court of the United States

ASTRA USA, INC., ET AL.,

PETITIONERS,

v.

COUNTY OF SANTA CLARA,

RESPONDENT.

**On Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA) AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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## INTEREST OF *AMICUS CURIAE*[1]

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies. *See* http://www.phrma.org/member_company_list (listing approximately 40 members, affiliates, and research associates). PhRMA advocates in support of public policies that encourage the discovery of life-saving and life-enhancing new medicines for patients by pharmaceutical and biotechnology research companies. In support of that mission, PhRMA members invested approximately $45.8 billion (of an industry total of approximately $65.3 billion) in 2009 in the discovery and development of new medicines. *See* 2010 Industry Profile, http://www.phrma.org/profiles_and_reports.

PhRMA monitors legal issues and cases that have significant impact on the pharmaceutical industry. To that end, PhRMA regularly files briefs in cases before this Court. *See, e.g.*, *Merck & Co., Inc. v. Reynolds*, 130 S. Ct. 1784 (2010) (No. 08-905); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006) (No. 05-130).

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[1] Pursuant to Rule 37.6, *amicus* states that no counsel for any party authored this brief in whole or in part, and that no person or entity other than *amicus* or its counsel made a monetary contribution to the preparation or submission of this brief. The parties have consented to the filing of this brief, and letters evidencing such consent have been filed with the Clerk pursuant to Rule 37.3.

The decision below has sweeping and unsettling consequences for pharmaceutical companies and the federal drug programs in which they participate. The Ninth Circuit armed 340B covered entities with a federal common law cause of action to sue drug manufacturers for alleged overcharges on the theory that 340B entities are third-party beneficiaries of contracts between manufacturers and the Department of Health and Human Services ("HHS"). Neither party to these contracts intended that 340B entities would be able to bring such damages actions, and neither party could have imagined that result given that the 340B statute concededly does not create such a right of action. The decision means that by entering into contracts with HHS to provide deep discounts or rebates on drugs purchased by the Nation's safety net providers, drug manufacturers subjected themselves unwittingly to unprecedented damages suits from the more than 14,500 entities that participate in the 340B program. In addition to the staggering litigation burdens posed by such suits, allowing non-statutory private damages suits in this complex and important field will undermine the uniformity and predictability that Congress sought to achieve by delegating the administration of the 340B program and the Medicaid rebate program to HHS.

## INTRODUCTION AND SUMMARY OF ARGUMENT

It is now settled that unless Congress intends to create a cause of action, "a cause of action does not exist and courts may not create one." *Alexander v. Sandoval*, 532 U.S. 275, 286-87 (2001). In no uncertain terms, this Court has emphasized that it

long ago "abandoned" the view that the federal courts' role is to attempt to improve statutory schemes by creating remedies that Congress did not provide. *Id.* at 287. It is undisputed that the statute at issue here, section 340B of the Public Health Service Act, 42 U.S.C. § 256b, does not create a private right of action allowing 340B entities to challenge the calculation of statutory ceiling prices through suits against participating drug manufacturers. That should have been the end of the analysis.

For the Ninth Circuit, the lack of a cause of action in the statute was instead an entry point into a freewheeling analysis of whether creating a federal common law cause of action would be "sensible." The Ninth Circuit's approach ignored the fundamental thrust of this Court's implied rights of action jurisprudence for the past 40 years: Under our system of separated powers, it is the job of Congress, not the federal courts, to decide what remedies are warranted. Congress not only has the constitutional authority to enact law, but is well-positioned to envision and address subsidiary questions like the statute of limitations, the extent of secondary liability, the appropriate forum, and the like. The lack of a statutory cause of action is thus the dispositive fact under core separation of powers principles — not a technicality to be waved aside en route to consideration of what remedies the court thinks should exist. That the Ninth Circuit resorted to federal common law to fashion the private right of action that Congress withheld exacerbates the error. The role of federal common law in the post-*Erie* world is extremely limited. Invoking that disfavored source of law to evade this Court's precedents

disfavoring non-statutory causes of action is doubly erroneous.

For these reasons, this Court should hold that where a federal statute does not create a private right of action, courts may not use federal common law to create a cause of action to enforce that statute. That holding flows from basic separation of powers principles and does not depend on whether it would be "sensible" to fashion a non-statutory cause of action in a given context or, rather, whether doing so would undermine or conflict with the statutory scheme. The courts' role is to ascertain the remedies that Congress has actually created, not to second-guess the wisdom of Congress's decision not to enact explicit remedies.

The Ninth Circuit's error here, however, went far beyond a "harmless" or abstract violation of the separation of powers. Federal common law actions challenging manufacturers' reported 340B price components will undermine the proper operation of both the 340B program and the much larger Medicaid rebate program by causing confusion and inconsistency and interfering with HHS's ability to reconcile competing interests and make reasonable, expert policy judgments. Remarkably, HHS explained to the Ninth Circuit that "allowing suits like this would threaten the orderly operation of *both* programs," U.S. CA9 Br. 19 (emphasis in original), and yet the Ninth Circuit decided for itself that empowering 340B entities to sue would be "sensible" and would help the Government by easing its enforcement burden. Even more remarkably, the Ninth Circuit did so without pausing to address the Government's view.

In short, even if it were permissible to create a federal common law claim to allow a purported third-party beneficiary to enforce some other statutory scheme, the statutory scheme at issue here cannot tolerate such judicial improvisation. The decision below does not merely conflict in theory with a presumed congressional intent; it promises direct, immediate, and far-reaching disruption of two vast and complex regulatory programs that Congress created. This Court therefore should reverse the decision below on any understanding of the authority of the federal courts to create federal common law claims to enforce federal statutes.

## ARGUMENT

### I. COURTS MAY NOT CREATE PRIVATE RIGHTS OF ACTION TO ENFORCE STATUTES THAT DO NOT CREATE PRIVATE RIGHTS OF ACTION.

#### A. This Court's Precedents Prohibit Fashioning A Private Cause Of Action That Congress Has Not Provided.

The Ninth Circuit's decision "revert[s] ...to the understanding of private causes of action that held sway 40 years ago." *Alexander v. Sandoval*, 532 U.S. 275, 287 (2001). In a long line of authority since *Cort v. Ash*, 422 U.S. 66 (1975), this Court has consistently and ever more emphatically repudiated the approach of *J.I. Case Co. v. Borak*, 377 U.S. 426 (1964). The guiding principle of the *Borak* era was that it was "the duty of the courts to be alert to provide such remedies as are necessary to make effective the congressional purpose." *Id.* at 433. The courts have long since gone off alert. *See Sandoval*,

532 U.S. at 175 ("We abandoned that understanding ... and have not returned to it since.").

In case after case, this Court has rejected judicial efforts to infer private rights of action and remedies where the statute provides no cause of action. *See, e.g.*, *Sosa v. Alvarez-Machain*, 542 U.S. 692, 727 (2004); *Sandoval*, 532 U.S. at 287-88; *Cent. Bank of Denver, N.A. v. First Interstate Bank of Denver, N.A.*, 511 U.S. 164, 173 (1994); *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134, 148 (1985); *Touche Ross & Co. v. Redington*, 442 U.S. 560, 568 (1979). The Court has rebuffed appeals to generalized "remedial purposes" of statutes as a way to go beyond or purport to improve upon statutory schemes as they were actually enacted. *See, e.g.*, *Touche Ross*, 442 U.S. at 578. And the Court has clarified over and over again that the "ultimate issue" is whether Congress created the asserted right or remedy. *Sierra Club*, 451 U.S. at 293; *see also Va. Bankshares, Inc. v. Sandberg*, 501 U.S. 1083, 1102 (1991) ("recognition ... must ultimately rest on congressional intent to provide a private remedy"); *Nw. Airlines, Inc. v. Transport Workers*, 451 U.S. 77, 91 (1981) ("ultimate question ... is whether Congress intended to create the private remedy"); *Transamerica Mortg. Advisors, Inc. v. Lewis*, 444 U.S. 11, 15 (1979) ("what must ultimately be determined is whether Congress intended to create the private remedy"); *Touche Ross*, 442 U.S. at 578 ("ultimate question is one of congressional intent"). Rather than assuming the authority to decide what remedies are necessary or appropriate, federal courts now must limit themselves to ascertaining what remedies Congress created.

What was already "clear" in 1979, *Touche Ross*, 444 U.S. at 16, is pellucid in 2010: Today, "it is settled that there is an implied cause of action only if the underlying statute can be interpreted to disclose the intent to create one." *Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 164 (2008). Unless Congress intends to create a cause of action, "a cause of action does not exist and courts may not create one." *Sandoval*, 532 U.S. at 286-87.

These are not merely scattered or fact-bound decisions. They reflect instead fundamental separation of powers limits on the authority of the federal courts. Where a court recognizes a private right of action in the absence of congressional intent, it "'necessarily extends its authority to embrace a dispute Congress has not assigned it to resolve.'" *Stoneridge*, 552 U.S. at 164 (quoting *Am. Fire & Cas. Co. v. Finn.*, 341 U.S. 6, 17 (1951)); *see also Touche Ross*, 442 U.S. at 579 ("[W]e are not at liberty to legislate.... 'It is not for us to fill any *hiatus* Congress has left in this area.'") (citation omitted). As this Court has emphasized, the "decision to extend [a] cause of action is for Congress, not for us." *Stoneridge*, 552 U.S. at 165. Whether the court believes that Congress has made wise decisions about whether or how to extend a cause of action, or whether the court believes that it could improve upon the congressionally-enacted scheme, are simply not proper questions for the federal courts to ask.

This reluctance reflects not just the reality that only Congress has the constitutional authority to enact laws. It also reflects the practical reality that when Congress does actually enact a private cause of action, it generally explicitly anticipates and addresses subsidiary questions such as the statute of

limitations and the degree of secondary liability. When courts infer a cause of action that Congress has not expressly enacted, the courts cannot announce the appropriate statute of limitations or degree of secondary liability. Those issues must be resolved in subsequent cases based on default rules, because there is no clear congressional guidance on questions such as how long Congress would have wanted the statute of limitations to run for a cause of action it did not envision at all. In the Rule 10b-5 context, this Court has had to address the statute of limitations as a default matter, *Lampf, Pleva, Lipkind, Prupis & Petigrow v. Gilbertson*, 501 U.S. 350 (1991), then consider the constitutionality of Congress's effort to respond, *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211 (1995), and had to consider the extent of secondary liability not once, *Cent. Bank of Denver, supra*, but twice, *Stoneridge, supra*.

In keeping with the fundamental nature of the limits on judicial authority to create non-statutory rights of action, this Court has adhered to this restrained approach in a variety of contexts. For example, even where *stare decisis* has left older decisions recognizing implied rights of action in place, the Court has consistently applied the modern rules to questions about the extension or application of those rights of action. *See, e.g., Stoneridge*, 552 U.S. at 165 ("Though it remains the law, the § 10(b) private right should not be extended beyond its present boundaries.").

The Court has also extended the principle beyond the statutory context to cases involving alleged constitutional violations. In *Correctional Services Corporation v. Malesko*, 534 U.S. 61 (2001), a federal inmate sought a *Bivens* damages remedy

against a government contractor running a halfway house. Emphasizing that the Court had "'abandoned' the view of *Borak* decades ago" and disavowed any "previous willingness to imply a cause of action where Congress has not provided one," the Court declined to create a *Bivens* remedy. *Id.* at 67 n.3, 70. In the years since *Malesko*, the Court has further reinforced that reluctance to extend *Bivens* remedies. *See Wilkie v. Robbins*, 551 U.S. 537, 562 (2007) (damages remedy "may come better, if at all, through legislation" rather than *Bivens*); *cf. Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1948 (2009) ("implied causes of action are disfavored").

Moreover, the Court has applied the same separation of powers principles in deciding which federal statutes are enforceable in private damages suits brought under 42 U.S.C. § 1983. *See Gonzaga Univ. v. Doe*, 536 U.S. 273, 290 (2002) ("if Congress wishes to create new rights enforceable under § 1983, it must do so in clear and unambiguous terms — no less and no more than what is required for Congress to create new rights enforceable under an implied private right of action").

Despite this clear and consistent precedent, the Ninth Circuit viewed the conceded lack of a statutory private right of action to enforce the 340B statute as an invitation to judicial creativity, rather than as the end of the analysis. *See* Pet. App. 22a (acknowledging respondent's concession that "there is no private federal cause of action under § 256b," the 340B statute). The Ninth Circuit noted that drug manufacturers' statutory drug pricing obligations are incorporated by reference in Pharmaceutical Pricing Agreements ("PPAs") — form contracts between HHS and the manufacturers

participating in the 340B program. And it held that although the 340B statute afforded no such action, 340B entities could bring breach-of-contract claims, as third-party beneficiaries of the PPAs under federal common law, to enforce the statutory requirements that manufacturers provide appropriate discounts to 340B entities.

In so holding, the Ninth Circuit openly appealed to what it viewed as the purposes of the 340B statute and "sensible" enforcement policy. Lamenting what it perceived as a "paucity of statutory authority" to enforce pricing obligations against drug manufacturers, the Ninth Circuit reasoned that allowing 340B entities to sue as third-party beneficiaries of the PPAs presented "one way of ensuring that drug companies comply with their obligations under the program." Pet. App. 26a-27a. Private suits, it suggested, were a "'sensible'" alternative to placing the entire "'burden of enforcement'" on HHS, *id.* (quoting *Price v. Pierce*, 823 F.2d 1114, 1121 (7th Cir. 1987)), and would be "compatible" with the statutory scheme. Pet. App. 26a.[2]

This approach harkens back to the discredited view of *Borak* that courts may create private rights of action based on nothing more than their own view of what might generally advance purposes reflected

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[2] The Ninth Circuit could assert that it was helping the Government by lightening its enforcement burden only because it ignored the Government's *amicus* brief explaining that the Government did not want any such "help" and that private common law suits "would conflict with Congress's comprehensive administrative and enforcement scheme." U.S. CA9 Br. 13.

in the statutory scheme. As explained in the next section, such a private right of action is not at all "compatible" with the 340B program (or the Medicaid rebate program to which the 340B program is inextricably linked), *see infra* at 18-27, but the proper question is whether Congress created such rights of action, not whether they are compatible with what Congress intended. *Sandoval*, 532 U.S. at 286-87 (absent statutory cause of action, "courts may not create one, no matter how desirable that might be as a policy matter, or how compatible with the statute").

Moreover, the Ninth Circuit's reasoning that "[a]lthough the statute ... does not create a federal private cause of action, allowing Santa Clara's contract claim to go forward is consistent with Congress' intent," Pet. App. 29a, is a non-sequitur. If "Congress' intent" had been to permit such a cause of action, Congress would have created it. The conceded failure by Congress to create a private cause of action in the 340B statute is a clear indication that "Congress' intent" was *not* to create such a cause of action. *See Wilson v. Libby*, 535 F.3d 697, 709 (D.C. Cir. 2008) ("it is where Congress has intentionally withheld a remedy that we must most refrain from providing one"), *cert. denied*, 129 S. Ct. 2825 (2009). Yet the Ninth Circuit treated the absence of statutory remedies as a reason why it was necessary to conjure a new remedy through federal common law. *See* Pet. App. 25a (lamenting that the 340B statute "does not 'expressly provide' any remedies to covered entities"). In refusing to allow the statutory scheme as actually enacted to slow it down, the Ninth Circuit turned back the clock on the past forty years of this Court's precedents.

### B. The Limited Role Of Federal Common Law Post-*Erie* Does Not Include Circumventing This Court's Implied Rights Of Action Jurisprudence.

1. The Ninth Circuit's approach to federal common law would render this Court's carefully delineated limits on implied rights of action for naught. Calling an implied cause of action a federal common law action does not change the fundamental reality that the Ninth Circuit created a cause of action that Congress chose not to enact. 340B entities certainly do not care what label is put on their federal cause of action. It is quite a consolation prize to be told that although they cannot bring a statutory cause of action for damages to enforce the statutory pricing requirements, they may bring an action for the same relief, to enforce the identical statutory requirements (which the statute dictates be included in the PPAs between the companies and HHS), through the guise of the federal common law of contracts. This Court has not gone to great lengths to chart a new course concerning the role of the federal courts vis-à-vis Congress and the limits on implied rights of action only to have lower courts opt out of those separation of powers principles through the simple expedient of invoking federal common law.

2. That such circumvention is inappropriate is even clearer given the extremely limited role of federal common law in the post-*Erie* era. Although the statement in *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938), that "[t]here is no federal general common law" remains an overstatement, the federal common law authority of the federal courts in the post-*Erie* world is extremely limited and, of course, is

subject to "'the paramount authority of Congress.'" *Nw. Airlines*, 451 U.S. at 95 (citation omitted). Federal common law is thus a uniquely poor candidate for a vehicle to defeat Congress's choices about what enforcement mechanisms to create in a statute.

Three aspects of the decision below aptly illustrate the dangers of the model of judicial circumvention through federal common law. First, the Ninth Circuit entirely ignored the Government's unambiguous warning that judicially-created private rights of action would *not* improve upon the 340B program's regulatory scheme. The Government, in fact, warned that permitting private damages suits "would conflict with Congress's comprehensive administrative and enforcement scheme" and stated with perfect clarity that "HHS never imagined that a 340B entity could bring a third-party beneficiary lawsuit like [respondent's]." U.S. CA9 Br. 13, 21. Yet the Ninth Circuit failed even to acknowledge the Government's position, highlighting that what it described as "sensible" supplementation of the regulatory scheme made "sense" to the court — and the court alone. *See* Pet. App. 27a.

Second, the Ninth Circuit failed to acknowledge the vigorous enforcement mechanisms governing the Medicaid rebate program, to which the 340B program is inextricably linked. Respondent alleges that manufacturers miscalculated or misreported 340B ceiling prices. But the two critical components of 340B ceiling prices — Average Manufacturer Price ("AMP") and Best Price ("BP") — derive directly from the Medicaid rebate program. AMP and BP, created under the Medicaid rebate program before the 340B program existed, are the key inputs to calculating

the rebates owed to States for covered outpatient drugs. *See* 42 U.S.C. §§ 1396r-8(c)(1)(A)-(C), 1396r-8(c)(3). AMP and BP are determined for use in the Medicaid rebate program and simply carried over to be used in the 340B program.

Viewed in context, then, Congress's decision not to create a private right of action for 340B entities makes eminent sense. The Medicaid rebate program has its own comprehensive enforcement scheme governing the calculation of AMP and BP that effectively serves to protect 340B entities. When Congress legislates concerning a complex statutory scheme, it can take the complex whole into account. A court confronted with a demand to create a new right of action in a particular case, in contrast, does not have the whole picture of the regulatory program or programs that might be affected by such a resort to federal common law. The Ninth Circuit's mistaken focus on the 340B program in isolation, divorced from the Medicaid rebate program, is a powerful demonstration of the risks in allowing ad hoc judicial determinations about what tinkering with complex statutory schemes is "sensible."

Third, the Ninth Circuit also ignored the existence of the False Claims Act ("FCA") — an express statutory cause of action designed precisely to ensure fair dealing in contractual undertakings with the Government. The FCA provides a highly potent private right of action for damages. Anyone can sue as a "relator" in the name of the United States, even without suffering individual injury. *See Vt. Agency of Natural Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 769 (2000). On top of treble damages, the FCA provides for penalties, and prevailing relators win up to 30% of the "proceeds of the action or

settlement" as a bounty, plus their attorney's fees. 31 U.S.C. §§ 3729(a), 3730(d)(2). Recoveries under the FCA in recent years have totaled in the billions. *See* U.S. Dep't of Justice, *Fraud Statistics*, http://www.justice.gov/opa/pr/2008/November/fraud-statistics1986-2008.htm. To be sure, respondent could not satisfy (*inter alia*) the demanding pleading or scienter standards set forth in Fed. R. Civ. P. 9(b) and § 3729(b)(3), respectively.[3] But an inability to satisfy the standards actually set by Congress is neither an invitation to nor a justification for judicial creation of a new claim.[4]

The critical point is that Congress has explicitly enacted a broadly applicable statutory cause of action that substantially overlaps with the federal common law action the Ninth Circuit created. The existence of that statutory cause of action not only belies the Ninth Circuit's suggestion that there was a void that needed filling. It also underscores Congress's manifest ability to enact powerful enforcement mechanisms in clear terms when it wishes to do so. Congress, in short, understands that it is responsible for creating private rights of action

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[3] Respondent initially brought a claim under California's FCA, which tracks the federal FCA, but abandoned it after the district court dismissed it twice. Having failed to satisfy the statutory standards, respondent then devised its third-party-beneficiary theory. *See* Pet. App. 7a, 99a-100a.

[4] Congress's specification of a heightened pleading standard and a demanding scienter requirement in the FCA is an illustration of the broader point that when Congress creates a cause of action, it can resolve important questions about the contours of that cause of action. A court inferring a private right of action from congressional silence cannot do so.

to enforce federal law, no less than it is responsible for enacting the underlying federal laws. *Sandoval*, 532 U.S. at 286. It unfairly and inappropriately disrespects Congress's constitutional role for a court to step in and create a non-statutory remedy on the rationale that Congress did not do its job.

3. The Patient Protection and Affordable Care Act ("PPACA"), enacted in March 2010, is a case in point illustrating the role of Congress, not the courts, to decide what enforcement mechanisms to create in the context of the specific programs at issue in this case. In the PPACA, Congress created a number of new 340B administrative enforcement mechanisms and lodged them within HHS, rather than creating a private right of action to authorize litigation directly in the courts. Three are of particular relevance. First, Congress directed HHS to establish a mandatory administrative process to resolve claims by 340B entities that manufacturers overcharged them — precisely the kind of claim at issue here. Pub. L. No. 111-148, § 7102(a), 124 Stat. 119 (2010) (adding 42 U.S.C. § 256b(d)(3)). Second, Congress empowered HHS to impose civil money penalties on drug manufacturers of up to $5,000 per instance of overcharging of a 340B covered entity. *Id.* (adding 42 U.S.C. § 256b(d)(1)(B)(vi)).[5] Third, Congress directed HHS to develop "a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers ... and charged to

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[5] HHS solicited input from interested parties on September 20, 2010. 75 Fed. Reg. 57,233. The comment period concerning the mandatory dispute resolution and civil money penalties provisions closes on November 19, 2010.

covered entities." 42 U.S.C. § 256b(d)(1)(B)(i). The Secretary is charged with developing precise standards for the calculation of ceiling prices, comparing reported ceiling prices with those HHS calculates itself, performing spot checks on 340B sales transactions, and inquiring into the cause of reported pricing discrepancies. *Id.* Rather than validate respondent's approach and confer to juries across the Nation the task of resolving complex disputes about prices reported in these regulatory programs, Congress vested the resolution of those disputes in the expert agency, with the agency's decisions reviewable in court.

The PPACA reinforces that Congress has a broader range of potential remedies available to it than the courts have using the relatively blunt instrument of the federal common law. It also reinforces Congress's ability to address subsidiary issues like the proper forum, exhaustion, and the like. Congress's institutional competence and its careful attention to the precise issue here should dispel any notion that Congress needs or wants the courts' "help" in refashioning Congress's handiwork in ways the courts think seem sensible.

* * * *

For all these reasons, the decision below exemplifies why courts are poorly equipped to resort to federal common law in an effort to "improve upon the statutory scheme that Congress enacted into law." *Touche Ross*, 442 U.S. at 578; *see also Wilkie*, 551 U.S. at 562 ("'Congress is in a far better position than a court to evaluate the impact of a new species of litigation'") (citation omitted). When this Court pronounced that it had sworn "off the habit of

venturing beyond Congress's intent" when it comes to private rights of action and declined "to have one last drink," it surely did not intend to abandon all temperance if the label on the bottle were switched to the "federal common law." *Sandoval*, 532 U.S. at 287. This Court should not allow federal common law to become an escape hatch from this Court's precedents limiting non-statutory rights of action.

## II. A PRIVATE RIGHT OF ACTION FOR 340B ENTITIES WOULD UNDERMINE THE STATUTORY SCHEME.

For the reasons just discussed, it violates fundamental separation of powers principles for a federal court to take it upon itself to supplement the remedies that Congress has created. When a statute does not create a private right of action, courts may not create one, whether under the rubric of implied statutory rights of action or federal common law. That fundamental limitation is true even where it would, in fact, be "sensible" as a policy matter to provide an additional remedy and the additional remedy under consideration would not undermine the statutory scheme. The Court thus should reverse the Ninth Circuit's decision even without any need to consider the intricacies of the 340B and Medicaid rebate programs or the sensibility of the Ninth Circuit's new federal common law remedy. In all events, however, this Court should reverse the decision below because it is clear that allowing third-party beneficiary damages claims would significantly undermine the orderly operation of the 340B and Medicaid rebate programs and that the federal common law right of action that the Ninth Circuit created is incompatible with the statutory scheme.

### A. Private Damages Actions Would Undermine HHS's Exclusive And Expert Oversight Over The 340B Ceiling Price Components.

Arming 340B covered entities with private rights of action to enforce 340B ceiling prices against drug manufacturers would disrupt HHS's orderly administration of not one, but two major federal health care programs: the 340B program and the Medicaid rebate program. Congress made a deliberate decision to delegate to HHS the exclusive authority to audit manufacturers' reported AMPs and BPs. That this was Congress's deliberate decision should be sufficient, under basic separation of powers principles, to insulate it from judicial efforts at improvement. In the context of the programs at issue, moreover, Congress's decision to opt for orderly, expert administration by HHS rather than private damages actions by purported third-party beneficiaries was eminently sensible.

Respondent's claim is that nine drug manufacturers miscalculated the AMPs and BPs — the key components of 340B ceiling prices — of covered outpatient drugs, resulting in 340B entities in California being overcharged. As noted above, AMP and BP originated in the Medicaid rebate program, where they are the two critical inputs to calculating rebates owed to States for covered outpatient drugs. *See* 42 U.S.C. §§ 1396r-8(c)(1)(A)-(C), 1396r-8(c)(3). The 340B program merely carries over the AMP and BP from the Medicaid rebate program; indeed, the 340B program expressly incorporates the drug pricing provisions of the Medicaid rebate program. *See* 42 U.S.C. § 256b(a) (incorporating by reference 42 U.S.C. § 1396r-8).

Because AMP and BP continue to be calculated and reported pursuant to the Medicaid rebate program, the Ninth Circuit's apparent belief that the 340B statute gives HHS insufficiently robust enforcement authorities misses the point. As the Government explained in its *amicus* brief below, by "focusing on ... the 340B statute, [respondent] ignores the important role that CMS and the Social Security Act play in the 340B program." U.S. CA9 Br. 27. The Ninth Circuit, unfortunately, did not address and did not appear to consider the Government's explanation.

The Medicaid rebate program "has clearly been committed to [HHS's] comprehensive regulatory authority" through the Centers for Medicare & Medicaid Services ("CMS"). *Id.* The program sets forth a detailed regulatory scheme by which HHS maintains rigorous oversight of AMPs and BPs. The program obligates drug manufacturers to report AMP and BP at specified intervals to CMS. *See* 42 U.S.C. § 1396r-8(b)(3)(A). HHS enjoys exclusive authority to audit those reported AMPs and BPs. Congress has directed HHS to promulgate regulations offering guidance on how to calculate AMP correctly. *See* Pub. L. No. 109-171, § 6001(c)(3)(B), 120 Stat. 56 (2006); 42 C.F.R. §§ 447.500-447.520. Congress has supplied HHS with enforcement tools to investigate manufacturers' reported AMP and BP figures. *See* 42 U.S.C. § 1396r-8(b)(3)(A)-(B). Congress has also authorized HHS to impose monetary penalties if the reported price components are untimely or false, *see id.* § 1396r-8(b)(3)(B)-(C), or to pursue False Claims Act remedies through the Department of Justice. *See id.* § 1396r-8(b)(3)(C)(ii). And Congress has empowered

HHS to impose the ultimate sanction if manufacturers fail to submit reports, submit false information, or otherwise fail to comply with the Medicaid and 340B statute's requirements — it can terminate the manufacturer's eligibility for Medicaid. *See id.* § 1396r-8(b)(4)(B).

Viewing the 340B program in conjunction with the Medicaid rebate program, then, it is plain that HHS possesses and exercises comprehensive oversight authority of the 340B ceiling price components. In enacting this scheme, Congress recognized that HHS is uniquely equipped to handle the myriad technical issues involved in the calculation of AMP and BP, make reasonable policy judgments, and balance competing interests. In centralizing oversight in one agency, moreover, Congress understood pharmaceutical companies' need for uniform and predictable standards and the need for exclusive control by an expert agency if there is to be any hope of achieving uniformity and predictability.

The Ninth Circuit's creation of a federal common law right of action to litigate the proper calculation of AMP and BP radically undermines that regulatory scheme. Instead of a regime where HHS can bring to bear its expertise and make reasonable decisions about how to resolve the significant ambiguities and policy issues attendant to AMP and BP calculation in light of competing interests, juries across the Nation would render separate and likely inconsistent verdicts reflecting their views about how AMP and BP should be determined.

This invitation to inconsistency is incompatible with the very nature of the 340B and Medicaid

rebate programs and the role of AMP and BP in those programs. At any given time, there can only be one AMP and one BP for a drug. If a court decides at the behest of a 340B entity like respondent that a manufacturer should calculate AMP or BP in a specific way, that should control for the Medicaid rebate program. *See* 42 U.S.C. § 256b(b). If another court decides that AMP or BP should be calculated in even a slightly different way, manufacturers — and HHS — will face inconsistent mandates. And because the 340B and Medicaid rebate programs are conjoined, all the uncertainty and inconsistency that would result from private damages actions would affect both programs. That is why HHS warned that "allowing suits like this would threaten the orderly operation of *both* programs." U.S. CA9 Br. 19 (emphasis in original). The prospective remedy that Congress actually provided ameliorates these problems by funneling all decisions through the administrative process. That decision further underscores the imprudence of the Ninth Circuit's litigation-first approach.

### B. Private Damages Actions By Thousands Of 340B Entities Are The Antithesis Of Uniformity And Predictability.

Congress's decision to delegate exclusive oversight over AMP and BP to HHS makes perfect sense given the highly technical nature of these drug pricing calculations and the critical need for uniformity. Determining AMPs and BPs is an intricate and complex enterprise occupying enormous resources. Approximately 150 innovator drug manufacturers determine and report BP every calendar quarter for more than 6,300 drug products. For over 25,000 products, these manufacturers and

others calculate and report AMP for each month *and* each quarter. Every manufacturer of an innovator prescription drug must report 16 AMPs and four BPs annually for every dosage form and strength of that drug. PhRMA members calculate and report many thousands of these Medicaid price points each year. And AMPs and BPs are determined with exacting precision to six decimal places — one ten-thousandth of a penny. Manufacturers devote vast amounts of resources to the determination and reporting of AMP and BP. They staff entire departments devoted to the calculation of accurate reportable prices. They install and maintain costly and advanced computer systems to track sales, customers, adjustments, discounts, rebates, price concessions, and hundreds of other data points. They also enlist legal counsel and compliance officers, trained specifically in price reporting requirements, to develop and issue detailed internal policies and procedures. They then employ sophisticated consulting firms to test their companies' performance against those procedures. Government price reporting is a high-risk, high-intensity, high-stakes proposition for every drug maker that markets a product in the United States.

Because of the scope of the 340B and Medicaid rebate programs, the impact of AMP and BP calculations is staggeringly high. In 2003, for example, 340B entities enjoyed over $600 million in discounts. Medicaid rebates amounted to an estimated $6.5 billion. The Court does not need to look further than this case to see how burdensome and inapt third-party beneficiary damages suits are in this unique context. Respondent challenges all AMPs and BPs reported by nine large manufacturers over nearly eight years, implicating over 5,000

separate prices reported to CMS and hundreds of drug products. *See* Pet. App. 74a. To support its bald allegation that petitioners overcharged it in unspecified ways, respondent seeks nothing less than "[a]ll information . . . underlying [petitioners'] determinations of AMP and BP." *Id.* And that is but the "first stage of discovery." *Id.*

The enormous burdens imposed by this judicially-minted right of action would be a good enough reason by themselves not to create this new species of claim. *Cf. Wilkie*, 551 U.S. at 561. The reality is far worse, however. The premise of respondent's claim is that there is a single correct way to determine AMP and BP and that, if only manufacturers are dragged through enough discovery, the correct calculation of AMP and BP, and manufacturers' departures from it, will reveal themselves. That premise is entirely incorrect. The determination of AMP and BP is rife with unresolved ambiguity and necessary judgment calls on technical and policy issues.

As the Government explained in the court below, "manufacturers must contend with many difficult issues of interpretation, including questions surrounding the definition of a 'wholesaler,' questions about the meaning of 'retail class of trade,' and questions about a variety of complex pricing arrangements." U.S. CA9 Br. 4-5. Uniform HHS guidance helps to alleviate many complexities that bedevil the creation of drug pricing methodologies by improving manufacturers' ability to understand what is needed to come into compliance with ambiguous statutory and regulatory requirements. To that end, CMS has issued "Releases" containing ad hoc guidance over the years. *See* U.S. CA9 Br. 5. The agency's position can thus be tested in courts, subject

to the appropriate deference under the Administrative Procedure Act.

Notably, however, even CMS, notwithstanding its unique expertise, often struggles to issue definitive guidance on thorny questions relating to AMP and BP calculations that simply do not have straightforward answers. The broad requirements of the Medicaid rebate statute and the often opaque terms of CMS sub-regulatory guidance raise a host of such difficult interpretive issues. For example, manufacturers are required to allocate so-called "bundled" discounts across affected products, but what arrangements actually constitute bundles and how attendant price concessions are to be allocated remain persistent sources of confusion and uncertainty. When the agency finally published regulations, along with a 103-page preamble, in 2007 — for the first time since the program's genesis in 1991 — the regulations offered significant clarifications, but left many complexities unanswered. *See* U.S. CA9 Br. 29. Existing CMS guidance and "Releases," then, do not purport to provide manufacturers with comprehensive instructions.[6]

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[6] In light of the PPACA's amendments to the Medicaid drug rebate statute, CMS has withdrawn its now-outdated regulatory definition of AMP. 75 Fed Reg. 69,591 (Nov. 15, 2010) (withdrawing, *inter alia*, 42 C.F.R. § 447.504). CMS has stated that it "is committed to developing further regulations that will provide the necessary guidance to all parties impacted by the revisions made to the Medicaid Drug Rebate Program by the [PPACA]." *Id.* at 69,592-93. Until further guidance is issued, however, manufacturers face even greater uncertainty.

On questions as to which no specific CMS guidance yet exists, HHS's oversight responsibilities assume an even more critical role. HHS recognizes manufacturers' predicament and provides that under such circumstances, manufacturers are entitled to "make reasonable assumptions in [their] calculations of AMP and [BP]." Medicaid Drug Rebate Agreement § II(i), J.A. 78-79. Assigning those judgments to courts that are not steeped in the practical and technical issues involved in determining AMP and BP — and that are equipped with nothing more than the federal common law to make those judgments without meaningful guidance from Congress — is a recipe for rampant confusion and inconsistency.

In short, the federal common law "cure would be worse than the disease" that the Ninth Circuit sought to address. *Wilkie*, 551 U.S. at 561. Even if there could be some other regulatory context that could comfortably accommodate a judicially-created federal common law remedy, this is not it.

### C. Conflicting Interests Between States And 340B Entities Exacerbate The Problems With The Decision Below.

Part of the reason drug pricing components require HHS's exclusive, uniform oversight is that the interrelationship between the Medicaid rebate program and the 340B program means that the interests of States and 340B entities often conflict. HHS uses AMP both to set the amount manufacturers must pay in Medicaid rebates to States and to establish the 340B ceiling price that may be charged to 340B entities. Typically, the lower the AMP, the lower a product's price to a 340B

entity. But the higher the AMP, the more a state Medicaid agency typically receives in rebates from manufacturers. Thus, 340B entities have an interest in resolving ambiguities and technical issues in ways that would reduce AMP, while States have the opposite interest. This dynamic makes Congress's decision to confer the operation of these programs to a centralized, expert agency even more prudent. HHS can ascertain competing interests and balance them in making reasonable policy judgments in a way that a court armed with nothing more than federal common law simply cannot. And the existence of competing interests in how AMP and BP are determined heightens the risk that private damages actions will lead to inconsistent results.

The Ninth Circuit wholly missed this bigger picture because of its mistaken focus on the 340B program in isolation. Misunderstanding AMP and BP as metrics intended exclusively to benefit 340B entities, the Ninth Circuit failed to grapple at all with the complexities posed by the conflicting interests of States and the operation of the Medicaid rebate program. That broader context makes it even clearer that federal common law damages actions would conflict with the way Congress intended these important regulatory programs to function. And the Ninth Circuit's error in failing to understand that broader context reinforces why courts should not undertake to decide whether supplementing a statutory scheme with a new remedy is or is not sensible.

* * * *

When Congress does not create a private right of action to enforce a statute, the consequence is not to

open the door to a freewheeling federal common law inquiry into the wisdom of the omitted relief. Rather, the consequence of Congress's decision not to create a cause of action to allow 340B entities to enforce the drug pricing agreements between manufacturers and HHS is that "a cause of action does not exist and courts may not create one." *Sandoval*, 532 U.S. at 286-87. This Court should reverse the Ninth Circuit's decision both because the court lost sight of that fundamental principle of our system of separated powers and also because its decision will gravely and concretely undermine the statutory scheme that Congress created to regulate drug pricing.

## CONCLUSION

The decision below should be reversed.

Respectfully submitted,

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# AMICUS CURIAE BRIEF

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IN THE

# Supreme Court of the United States

ASTRA USA, INC., *et al.*,
*Petitioners,*

v.

COUNTY OF SANTA CLARA, On Behalf of Itself and All Others Similarly Situated,
*Respondent.*

**On Writ of Certiorari to the U.S. Court of Appeals for the Ninth Circuit**

## BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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## QUESTION PRESENTED

Whether, in the absence of a private right of action to enforce a statute, federal courts have the federal common law authority to confer a private right of action on non-parties to a contract that embodies the statutory requirements sought to be enforced, based on a theory that the non-parties are intended third-party beneficiaries of the contract.

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## INTERESTS OF *AMICI CURIAE*

The Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 States.[1] WLF defends and promotes free enterprise, individual rights, and a limited and accountable government.

In particular, WLF has devoted substantial resources over the years to opposing efforts to create new private rights of action based on federal common law. WLF has appeared before this and other federal courts in numerous cases to espouse its view that if new federal causes of actions are to be created, the impetus for doing so should come from Congress, not the courts. *See, e.g., Sosa v. Alvarez-Machain*, 542 U.S. 692 (2004); *Presbyterian Church of Sudan v. Talisman Energy, Inc.*, 582 F.3d 244 (2d Cir. 2009), *cert. denied*, 178 L. Ed. 2d 241 (2010).

WLF is concerned that if allowed to stand, the decision below will be cited in support of efforts to create new causes of action under a broad range of federal regulatory programs. WLF recognizes that federal courts have a responsibility, *in the absence of legislation*, to fashion federal common law in cases raising issues of uniquely federal concern. But where, as here, Congress has adopted legislation that speaks directly to the issue at hand (whether beneficiaries of federal health care statutes are entitled to file suit to

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. All parties have consented to the filing of this brief; letters of consent have been lodged with the clerk.

enforce the terms of those statutes), there is no appropriate role for judicially created federal common law.

WLF is filing this brief to promote the interests of the business community and the public at large. It has no direct interest, financial or otherwise, in the outcome of this lawsuit. Because of its lack of direct interest, WLF believes that it can assist the Court by providing a perspective distinct from that of any party.

## STATEMENT OF THE CASE

Respondent County of Santa Clara operates several medical facilities that qualify for special prescription drug price discounts under federal law. Santa Clara alleges that Petitioners (a large number of pharmaceutical manufacturers) failed to provided it with the discounts to which it was entitled. At issue before the Court is whether federal common law entitles Santa Clara to sue Petitioners to recover its alleged overpayment.

The price discount program is commonly known as the Section 340B program. Section 340B of the Public Health Service Act of 1992 (the "340B Act"), 42 U.S.C. § 256b, requires drug manufacturers that participate in the federal Medicaid program to offer discounted drug prices to certain hospitals and clinics, referred to as "Section 340B entities," that provide services to low-income individuals.[2] The Santa Clara

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[2] Drug companies that participate in Medicaid may charge Section 340B entities no more than the "ceiling price," 42 U.S.C.

medical facilities are among the thousands of Section 340B entities throughout the country.

The § 340B Act and the Medicaid Act also both require drug companies participating in Medicaid to sign a contract with the Secretary of Health and Human Services, in which they explicitly agree to comply with the § 340B Act's price ceiling. 42 U.S.C. §§ 256b(a)(1); 1396r-8(a)(1) & (5). Each of the Petitioners has signed this contract, known as the Pharmaceutical Pricing Agreement (PPA). *See* Pet. App. 165a-181a. All the PPA contracts contain uniform language drafted by the Secretary. The PPA provides, *inter alia*, that "[t]he Agreement shall be construed in accordance with Federal common law, and ambiguities shall be interpreted in the manner which best effectuates the statutory scheme." PPA § VII(g), Pet. App. 180a.

Alleging that Petitioners sold their drugs at prices that exceeded the price ceiling, Santa Clara filed suit to recover the overcharges, invoking a variety of legal theories. After the district court dismissed its complaint without leave to amend, Santa Clara appealed on a single claim only. It asserted that Petitioners had breached the PPA by charging prices in excess of the price ceiling, and that it was entitled to sue as an intended third-party beneficiary of the PPA.

Agreeing that Santa Clara had stated a valid breach of contract claim, the Ninth Circuit reversed and remanded. Pet. App. 1a-29a. The court determined that

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§ 256b(a)(1), a term whose statutory definition incorporates definitions and pricing methodology from the Medicaid Act.

the PPA should be analyzed under the federal common law of contracts. *Id.* at 8a-10a. It held that the federal common law of contracts provides that a non-contracting party is entitled to recover under a contract if he is an intended beneficiary of the contract. *Id.* at 10a. It then analyzed the PPA and concluded that the parties thereto "clearly intended to grant covered [§ 340B] entities enforceable rights as intended beneficiaries of the agreement." *Id.* at 13a.

The court accepted Santa Clara's concession that, in adopting the § 340B Act, Congress had not intended to create a private right of action under the Act. *Id.* at 22a & n.15. The court nonetheless held that the absence of a private right of action under § 340B did not affect its analysis regarding Santa Clara's breach of contract action. The court stated, "We presume that Congress legislates with the expectation that the principles of the federal common law 'will apply except when a statutory purpose to the contrary is evident.'" *Id.* at 23a (quoting *Astoria Fed. Savings & Loan Ass'n v. Solimino*, 501 U.S. 104, 108 (1991)). The court concluded that no such contrary purpose was evident because "[p]ermitting covered entities to sue as intended beneficiaries of the PPA is . . . wholly compatible with the Section 340B program's objectives." *Id.* at 26a.

## SUMMARY OF ARGUMENT

The Ninth Circuit's decision was based on a fundamental misunderstanding of federal common law. The court began by assuming that all actions alleging the breach of a contract to which the United States is a

party are governed by a federal common law of contracts unless Congress has made evident a contrary intent. Not discerning such an intent, the court proceeded to decide the case based on its understanding of federal common law principles, including the rights of intended third-party beneficiaries of a contract.

The appeals court's initial premise was mistaken: there is no transcendental body of federal common law awaiting to be applied to federal contracts. This Court has stated repeatedly that there is no federal general common law, and that the instances in which federal courts are called upon to formulate substantive rules of decision are few and restricted. Where a specific issue warrants creation of a federal rules of decision, Congress (not a federal court) is the most appropriate decisionmaker. Federal courts are to create federal common law only "in the absence of an applicable Act of Congress." *Clearfield Trust Co. v. United States*, 318 U.S. 363, 367 (1943). In this case, there never was an absence of "an applicable Act"; at the same time that Congress adopted the § 340B Act, it made clear that the Act's price ceiling provision was not to be privately enforceable in federal court. Thus, there was never a need to develop a federal common law with respect to the rights of third-party beneficiaries under the PPA, and there was no existing federal common law for Congress to displace.

The Ninth Circuit applied a presumption that federal common law remains in place unless a contrary congressional intent is "evident." Pet. App. 23a. The court's decision to apply that presumption was erroneous, even if one assumes that there were

background principles of federal common law to be applied here. This Court has explained that no presumption against displacement of federal common law comes into play unless the federal common law doctrine at issue is so well established that Congress can be assumed to have considered the impact of its legislation on that doctrine. In the absence in this case of a well-established federal common law doctrine, the presumption operates the other way: we start with the presumption that Congress, through its legislation, created the operative rule of decision.

In determining that Santa Clara stated a cause of action for breach of contract under a third-party beneficiary theory, the Ninth Circuit relied heavily on evidence that Congress adopted the § 340B Act (and required drug companies to sign the PPA) for the purpose of benefitting § 340B entities. But this Court has never deemed it decisive, in determining whether Congress intended to grant a private right of action to a class of plaintiffs, that Congress adopted the legislation at issue for the purpose of benefitting those plaintiffs. On numerous occasions the Court has concluded that Congress did not intend to bestow a private right of action on the intended beneficiaries of a statute. Accordingly, given that Congress, in adopting the § 340B Act, decided *not* to grant § 340B entities a private right of action to enforce the price ceiling, findings that the § 340B Act was adopted for the purpose of benefitting § 340B entities provide no legitimate basis for the Ninth Circuit's decision that the federal common law grants them a right of action to enforce the PPA.

## ARGUMENT

### I. THERE CAN BE NO BASIS FOR CREATING FEDERAL COMMON LAW RULES IN THIS CASE WHEN CONGRESS HAS ALREADY EXPRESSED ITS VIEWS REGARDING ENFORCEMENT OF THE § 340B ACT

The Ninth Circuit correctly determined that federal law governs Santa Clara's breach of contract claims. Pet. App. 8a. It is well accepted that, in light of the need for uniformity of decision, the interpretation of contracts to which the United States is a party presents a question of federal law:

> The purpose of the supremacy clause was to avoid the introduction of disparities, confusions, and conflicts which would follow if the Government's general authority were subject to local controls. The validity and construction of contracts through which the United States is exercising its constitutional functions, their consequences on the rights and obligations of the parties, the titles or liens which they create or permit, all present questions of federal law not controlled by the law of any State.

*United States v. County of Allegheny*, 322 U.S. 174, 183 (1944).

But rather than looking to Congress for guidance regarding the federal law governing this case, the appeals court turned first to federal common law. Pet.

App. 8a. In doing so, the Ninth Circuit displayed a fundamental misunderstanding of the nature of federal common law. There is no transcendental body of federal common law awaiting to be applied to federal contracts. Rather, even when dealing with issues that are uniquely federal, federal courts are authorized to adopt federal common law contracting rules only when Congress has not addressed the issue, and even then only as a stop-gap measure until Congress acts. Thus, in addressing legal issues arising under contracts mandated by the § 340B Act, the Ninth Circuit should have turned first to the § 340B Act for guidance.

This Court has stated repeatedly that there is no general federal common law and that federal courts do not possess a general power to develop and apply their own rules of decision. *Erie R. Co. v. Tompkins*, 304 U.S. 64, 78 (1938). When Congress has not spoken to a federal issue, federal courts may be called upon to develop federal common law to provide a rule of decision, but such instances are "few and restricted." *Wheeldin v. Wheeler*, 373 U.S. 647, 651 (1963). Any effort to fashion federal common law is "subject to the paramount authority of Congress," *New Jersey v. New York*, 283 U.S. 336, 348 (1931), and should only be resorted to "[i]n absence of an applicable Act of Congress." *Clearfield Trust*, 318 U.S. at 367. Federal courts "start with the assumption that it is for Congress, not federal courts, to articulate the appropriate standards to be applied as a matter of federal law." *City of Milwaukee v. Illinois*, 451 U.S. 304, 317 (1981).

The aversion to reliance on federal common law is based on separation-of-powers concerns. *Northwest*

*Airlines, Inc. v. Transport Workers Union of America*, 451 U.S. 77, 95 (1981) ("[W]e have consistently recognized that the federal lawmaking power is vested in the legislative, not the judicial, branch of government; therefore, federal common law is subject to the paramount authority of Congress."). As Justice Scalia has explained:

> The general rule, as formulated in *Texas Industries*[, *Inc. v. Radcliff Materials, Inc.*], 451 U.S. [630,] 640-641 [(1981)], is that "the vesting of jurisdiction in the federal courts does not in and of itself give rise to authority to formulate federal common law." This rules applies not only to applications of federal common law that would displace a state rule, but also to applications that simply *create a private cause of action under a federal statute*.

*Sosa v. Alvarez-Machain*, 542 U.S. 692, 741-42 (2004) (Scalia, J., concurring in part and concurring in the judgment) (emphasis added).

The Ninth Circuit began by assuming that all actions alleging the breach of a contract to which the United States is a party are governed by a federal common law of contracts unless Congress has made evident a contrary intent. Not discerning such an intent, the court proceeded to decide the case based on its understanding of federal common law principles, including the rights of intended third-party beneficiaries under a contract.

As the preceding case law indicates, the Ninth

Circuit's approach was backwards; it should first have searched for evidence that Congress had spoken to the issues. Had it done so, it would have realized that there never was an absence of "an applicable Act of Congress," *Clearfield Trust*, 318 U.S. at 367, and thus there was no need to turn to federal common law. The PPA, the contract on which Santa Clara bases its cause of action, exists solely by virtue of Congress's adoption of the § 340B Act. Accordingly, the appeals court should have turned first to the § 340B Act for guidance on federal law applicable to the PPA. As Santa Clara concedes, Congress decreed that the Act's price ceiling provision was not to be privately enforceable in federal court. Once that federal rule is established, there is no reason for a court to attempt to fashion any sort of federal common law rule with respect to the rights of third-party beneficiaries under the PPA; there is simply no gap in need of filling.

In support of its decision to fashion federal common law, the Ninth Circuit pointed to § VII(g) of the PPA, Pet. App. 180a, which provides that the PPA is to be construed "in accordance with Federal common law." *Id.* at 8a. But § VII(g) does not suggest that courts should resolve disputed issues by resorting to federal common law principles even when Congress has spoken to the issue. Moreover, the final clause of Section VII(g) – "ambiguities shall be interpreted in the manner which best effectuates *the statutory scheme*" (emphasis added) – makes clear that the Secretary understood that the PPA must be construed in conjunction with all provisions of the § 340B Act.

As Petitioners have emphasized in their brief,

numerous provisions of the § 340B Act (*e.g.*, emphasis on maintaining the confidentiality of pricing data, the availability of alternative enforcement mechanisms) make plain that Congress did not anticipate that § 340B entities would be permitted to state claims based on alleged violations of the price ceilings. Because Congress has spoken directly to the question of such lawsuits – and because Santa Clara admits that Congress did not intend to create a private right of action under § 340B Act – any attempt to fashion a federal common rule covering the same subject matter would be inappropriate.

## II. THE APPEALS COURT ERRED IN RELYING ON A PRESUMPTION AGAINST DISPLACEMENT OF FEDERAL COMMON LAW

The Ninth Circuit was unable to point to any evidence that either the Secretary or Petitioners actually intended to permit Santa Clara or any other § 340B entity to sue to enforce rights under the PPA. Rather, it was able to reach its conclusion that suit was authorized by: (1) adopting a presumption that Congress intended to authorize such suits; and (2) concluding that permitting such suits was "wholly compatible with the § 340 programs objectives." Pet. Pet. 23a, 26a. The court's decision to apply that presumption was erroneous.

The only circumstance under which the Court employs a presumption against displacement of federal common law occurs where "a common-law principle is well-established." *Astoria Fed. Savings & Loan Ass'n v.*

*Solimino*, 501U.S. 104, 108 (1991). The courts "may take as a given that Congress has legislated with an expectation" that any such well-established principle "will apply except 'when a statutory purpose to the contrary is evident.'" *Id.* (quoting *Isbrandtsen Co. v. Johnson*, 343 U.S. 779, 783 (1952). Even when the presumption applies, "long-established and familiar" federal common law principles will be deemed displaced even without a congressional statement "affirmatively proscrib[ing]" their use, so long as a federal statute "speak[s] directly to the question addressed by the common law." *United States v. Texas*, 507 U.S. 529, 534 (1993).

But the presumption has no application here because there is no well-established federal common law rule permitting suits by intended beneficiaries under contracts of this sort (*i.e.*, contracts mandated by a federal statute and intended to ensure compliance with a statutory requirement). Santa Clara has not pointed to any decisions of this Court or any federal court (other than the decision below) that invoked federal common law to authorize suit by a third-party beneficiary under such a contract. Petitioners have cited several decisions that suggest the absence of such a common law principle. *See, e.g., United States v. Erika, Inc.*, 456 U.S. 201, 211 n.14 (1982); *Univs. Research Ass'n, Inc. v. Coutu*, 450 U.S. 754 (1981).

In the absence of a well-establish federal common law rule granting a cause of action to third-party beneficiaries, the Ninth Circuit erred in applying the presumption. This Court recently explained, in rejecting an argument that Congress (when adopting a

tax lien statute) should be presumed not to have intended to overturn a supposed common law rule that tax liens do not apply to property owned as tenants in the entirety:

> The common-law rule was not so well established with respect to the application of a federal tax lien that we must assume that Congress considered the impact of its enactment on the question now before us. There was not much of a common-law background on the question of the application of federal tax liens.

*United States v. Craft*, 535 U.S. 274, 288 (2002).

Indeed, the presumption actually runs the other way: we start with the presumption that Congress, through its legislation, created the operative rule of decision on the federal question at issue here. The Court explained in *City of Milwaukee* that the presumption against displacement of common law arises primarily in cases in which a federal statute arguably displaces *state* common law; in those circumstances, federalism concerns counsel hesitation before a court determines that federal law displaces a well-established common law rule. *City of Milwaukee*, 451 U.S. at 316. But:

> Such concerns are not implicated in the same fashion when the question is whether federal statutory or federal common law governs, and accordingly the same sort of evidence of a clear and manifest purpose is not required. Indeed, as noted, in cases such as the present, "*we start with*

> *the assumption*" that it is for Congress, not federal courts, to articulate the appropriate standards to be applied as a matter of federal law.

*Id.* (emphasis added).

Lower federal courts have on occasion applied federal common law to grant a cause of action to third party beneficiaries under federal procurement contracts. *See, e.g., D & H Distributing Co. v. United States*, 102 F.3d 542 (Fed. Cir. 1997). But a federal procurement contract is of a fundamentally different nature than the PPA. Under a procurement contract, the government is entering the commercial marketplace to procure goods or services; the parties to such a contract can reasonably expect that their relationship is to be governed by the common-law commercial contracting principles dating back a thousand years, in the absence of an indication from Congress to the contrary. Thus, if the contract specifies that the proceeds of contract are to be paid to a third party, the contracting parties can reasonably be assumed to have intended that the third party may sue to enforce payment. *Id.* at 547. But contracts such as the PPA – under which a government requires contractors to agree to comply with pre-existing government regulations as a condition for continued participation in a government program – have no antecedents in the common law. Thus, when Congress adopted the § 340B Act, there was no well-established federal common law tradition governing how contracts mandated by the Act were to be construed. Under those circumstances there is no basis for presuming that federal common law governs how the PPA is to be construed in the absence of a congressional statement

that "speaks directly" to third-party beneficiary rights. The Ninth Circuit's ruling to the contrary cannot stand.

## III. THE APPEALS COURT PLACED UNDUE WEIGHT ON CONGRESS'S DESIRE TO BENEFIT SECTION 340B ENTITIES

In arriving at its decision, the Ninth Circuit relied heavily on its conclusion that the chief purpose, if not the exclusive purpose, of the § 340 Act was to provide a financial benefit to § 340B entities by lowering their prescription drug costs. *See, e.g.,* Pet. App. 15a. In light of that conclusion, the court held that permitting § 340B entities to bring suit for breach of contract was "wholly compatible with the § 340 programs objectives." Pet. Pet. 26a.

In so holding, the appeals court placed undue emphasis on Congress's evident desire to benefit § 340B entities. This Court has repeatedly made clear that the mere fact that a plaintiff is an intended beneficiary of a federal statute is insufficient to justify a conclusion that Congress intended to permit the plaintiff to file suit to enforce the statute.

On numerous occasions the Court has concluded that Congress did not intend to bestow a private right of action on the intended beneficiaries of a statute. For example, the Court held that Congress did not intend to create a private right of action for those injured due to violations of the Investment Advisers Act of 1940, 15 U.S.C. § 80b-1 *et seq.,* even though such individuals undoubtedly were the people Congress intended to protect when it adopted the Act. *Transamerica*

*Mortgage Advisors, Inc. v. Lewis*, 444 U.S. 11 (1979). Similarly, the Court held that Congress did not intend to create a private right of action under the Employee Retirement Income Security Act (ERISA) for a beneficiary of a disability income plan seeking to sue a plan fiduciary that breached its fiduciary duties to the beneficiary under ERISA, even though ERISA undoubtedly was adopted for the benefit of such beneficiaries. *Mass. Mut. Life Ins. Co. v. Russell*, 473 U.S. 134 (1985).

Congress no doubt adopted the § 340B Act for the benefit of Santa Clara and similarly situated medical providers, for the purpose of reducing their drug purchasing costs. Nonetheless, it has already been determined that Congress, despite its strong desire to benefit § 340B entities, did not intend to create a private right of action on their behalf. It makes little sense, therefore, to craft a federal common law rule granting § 340B entities the right to sue as third-party beneficiaries of the PPA, based on little more than evidence that the Congress and the Secretary drafted the PPA for the purpose of benefitting those entities.

In sum, given that Congress, in adopting the § 340B Act, decided *not* to grant § 340B entities a private right of action to enforce the price ceiling, findings that the § 340B Act was adopted for the purpose of benefitting § 340B entities provide no legitimate basis for the Ninth Circuit's decision that the federal common law grants them a right of action to enforce the PPA.

## CONCLUSION

The Washington Legal Foundation respectfully requests that the Court reverse the decision of the court of appeals.

Respectfully submitted,

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